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(54) **VASCULAR IMPLANT AND DELIVERY SYSTEM**

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(58) **Field of Classification Search**
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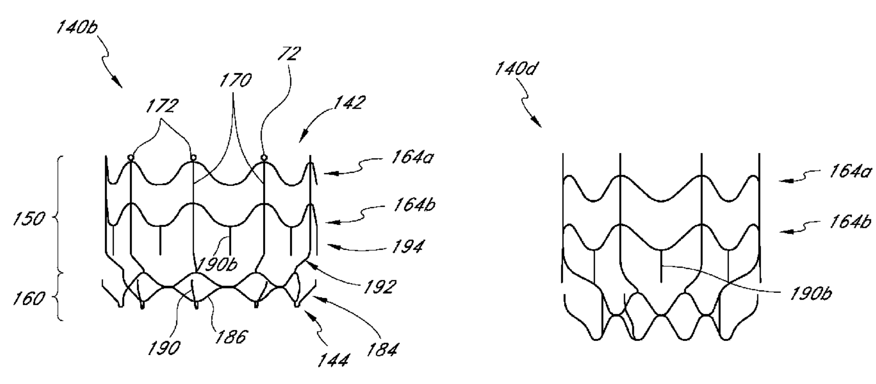
(57) **ABSTRACT**

A vascular implant for replacing a native heart valve comprises a self expanding stent supporting a valve body having leaflets. The stent preferably comprises an anchoring structure configured to prevent the implant from passing through the valve annulus. For delivery, the implant is compacted within a delivery device and secured at one end. During delivery the implant is partially released from the delivery device, and positioning of the implant can be verified prior to full release. The implant can be at least partially resheathed and repositioned if desired.

29 Claims, 45 Drawing Sheets



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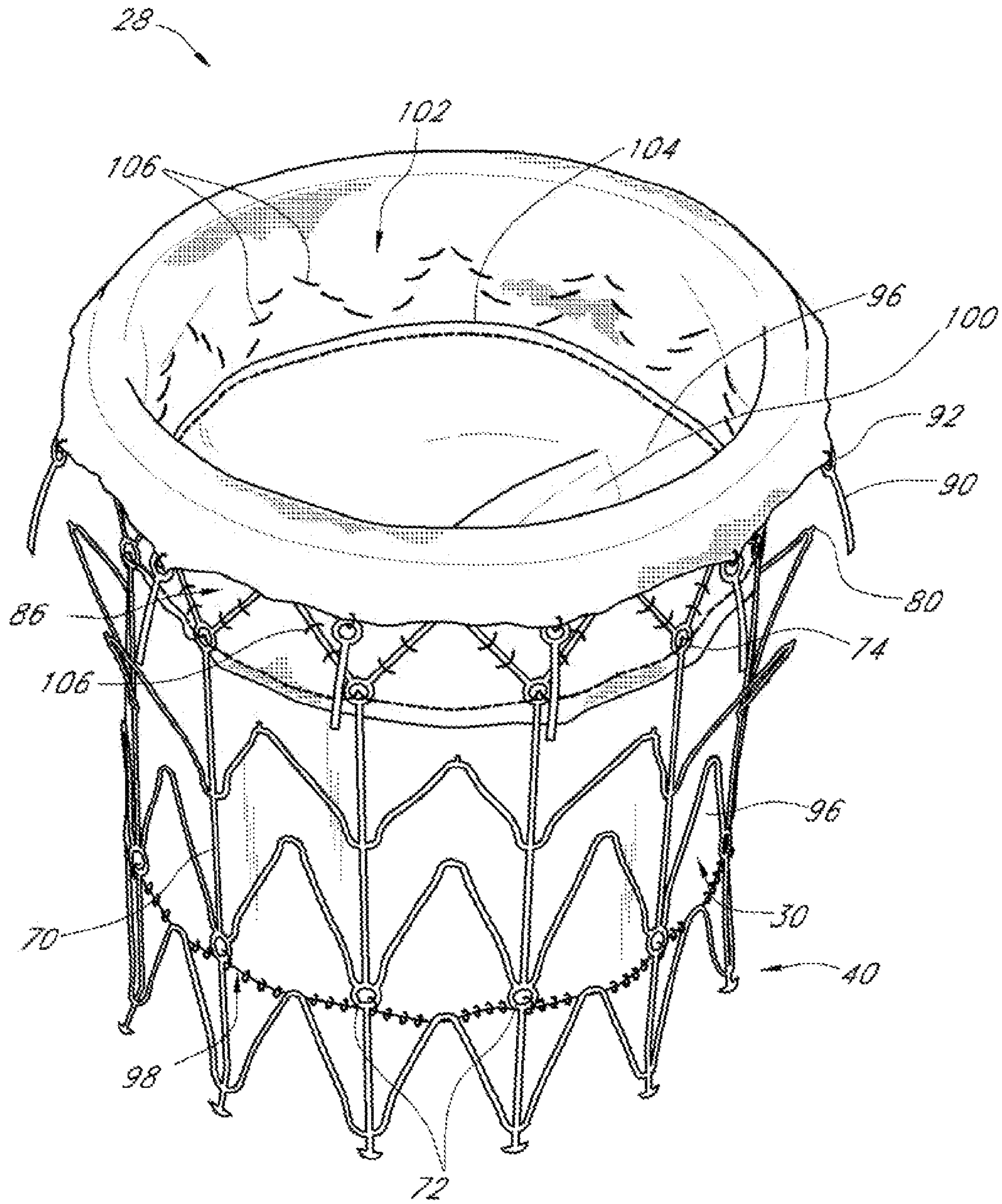

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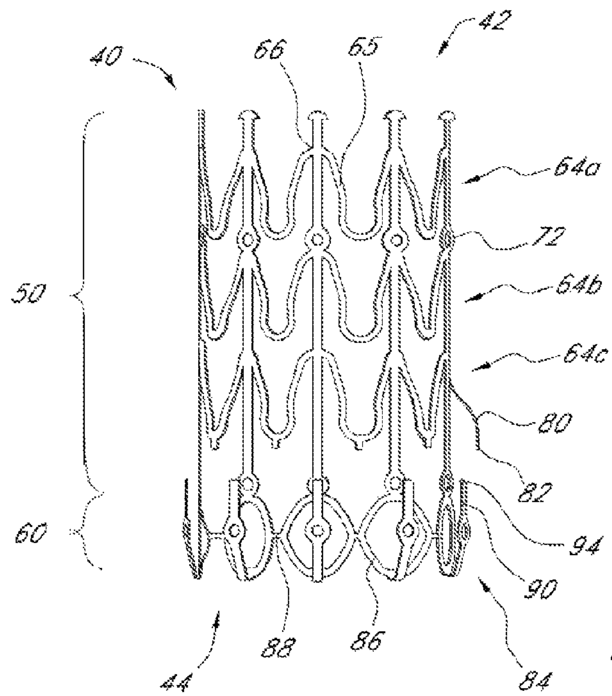
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FIG. 2A

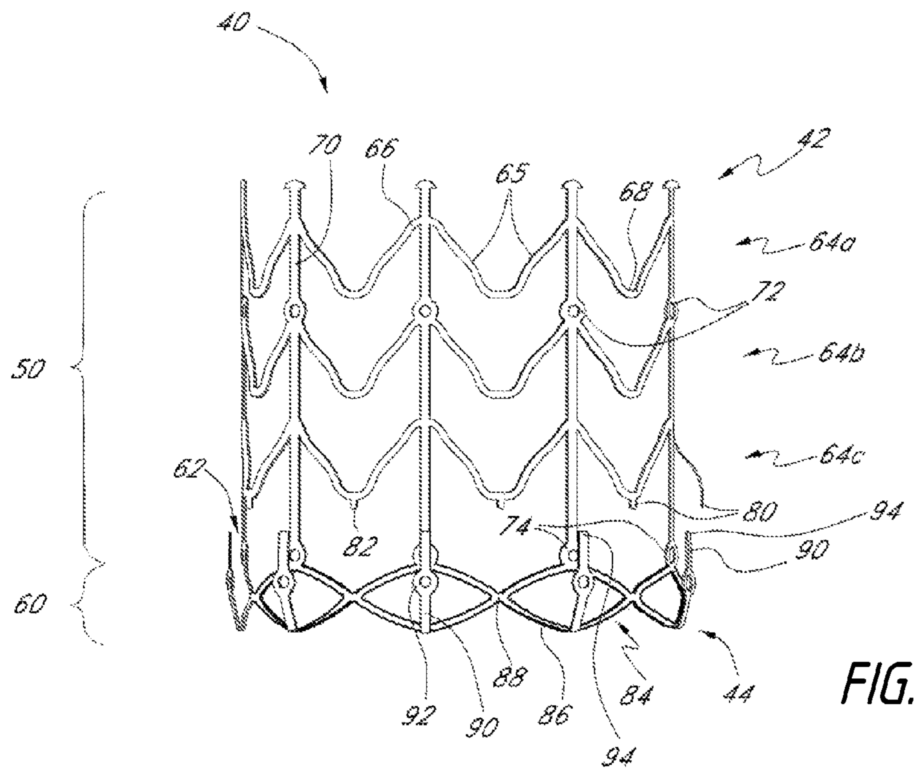
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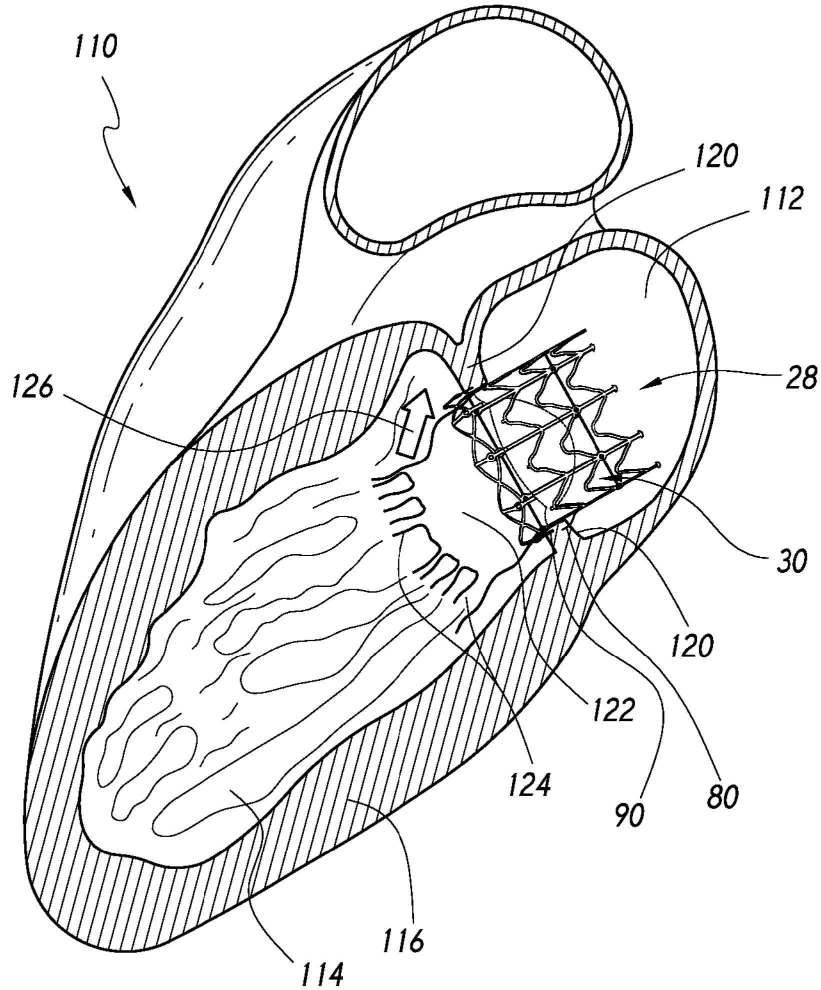
FIG. 2B



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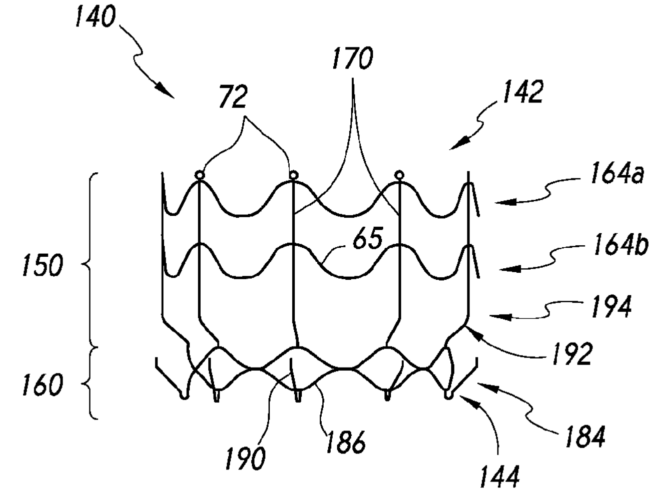
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FIG. 4A

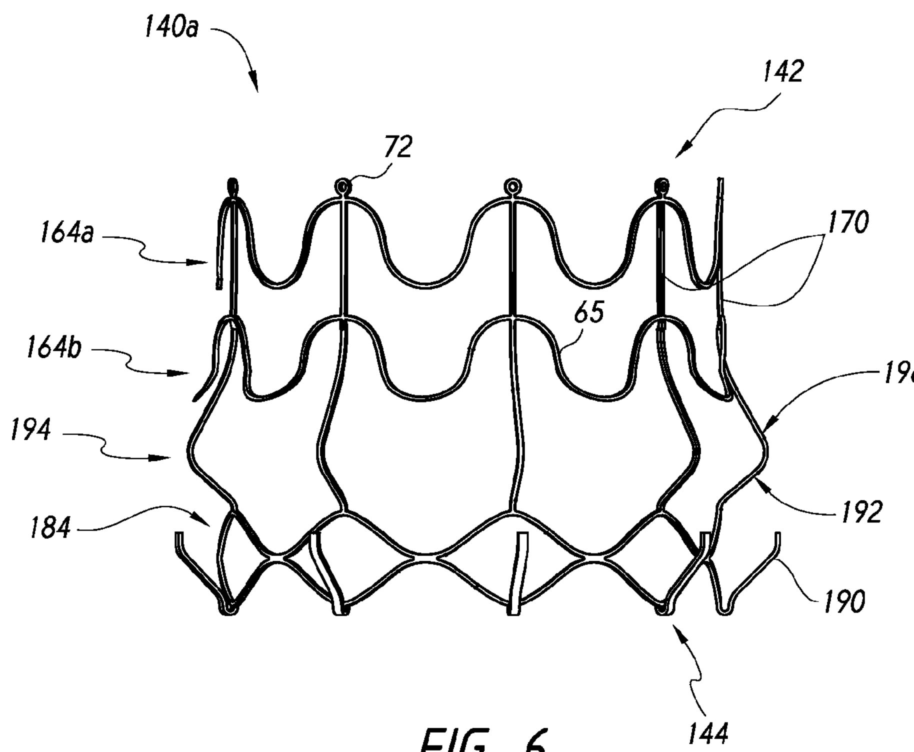
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FIG. 6

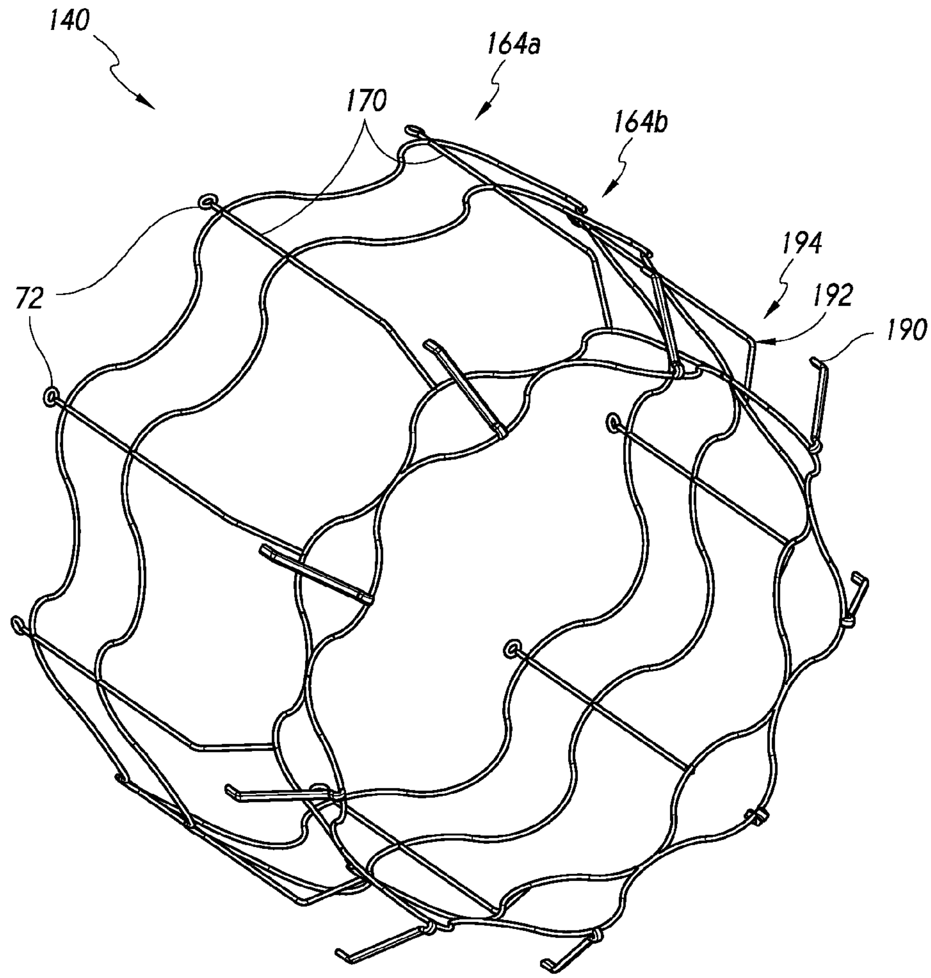


FIG. 4B

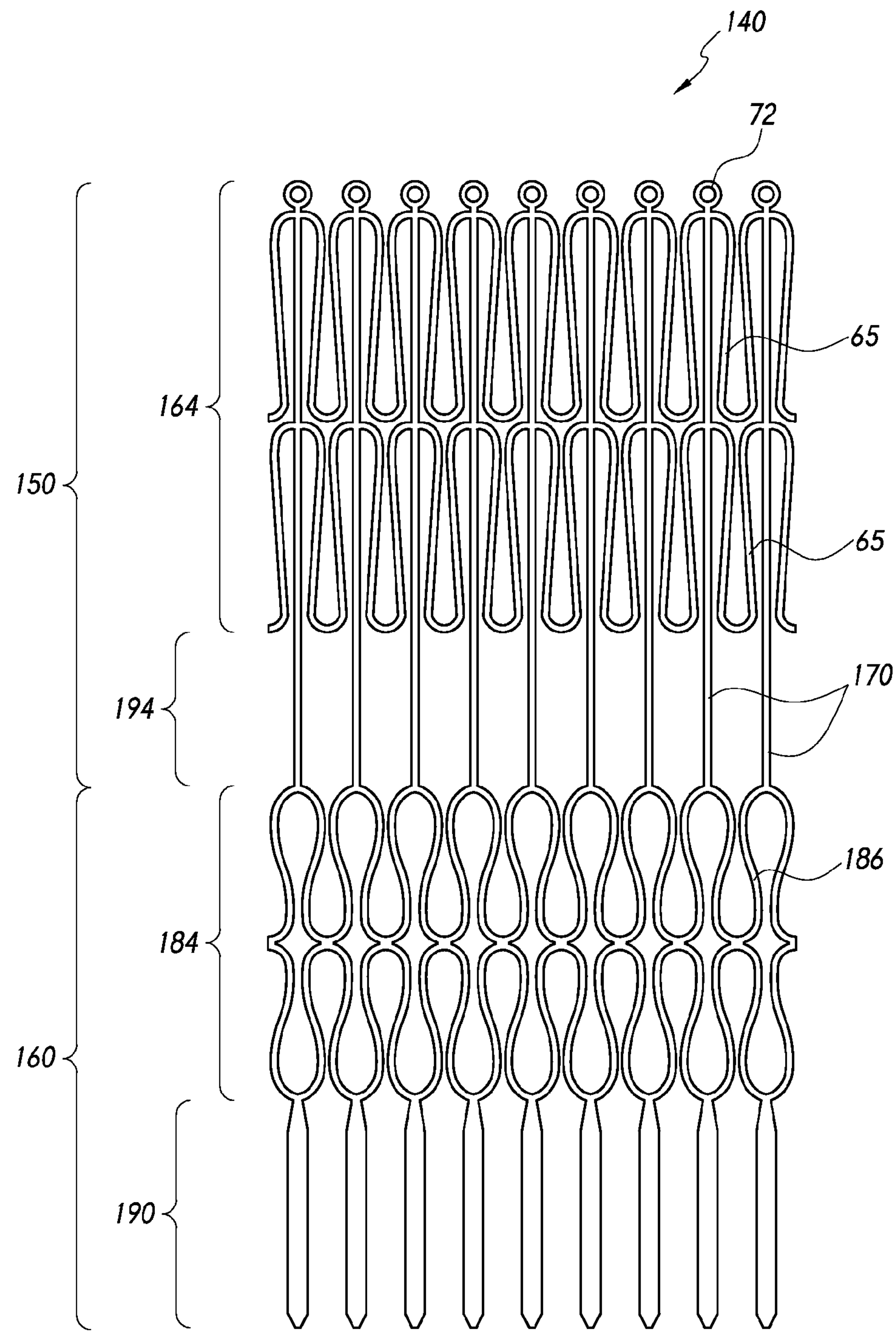


FIG. 5A

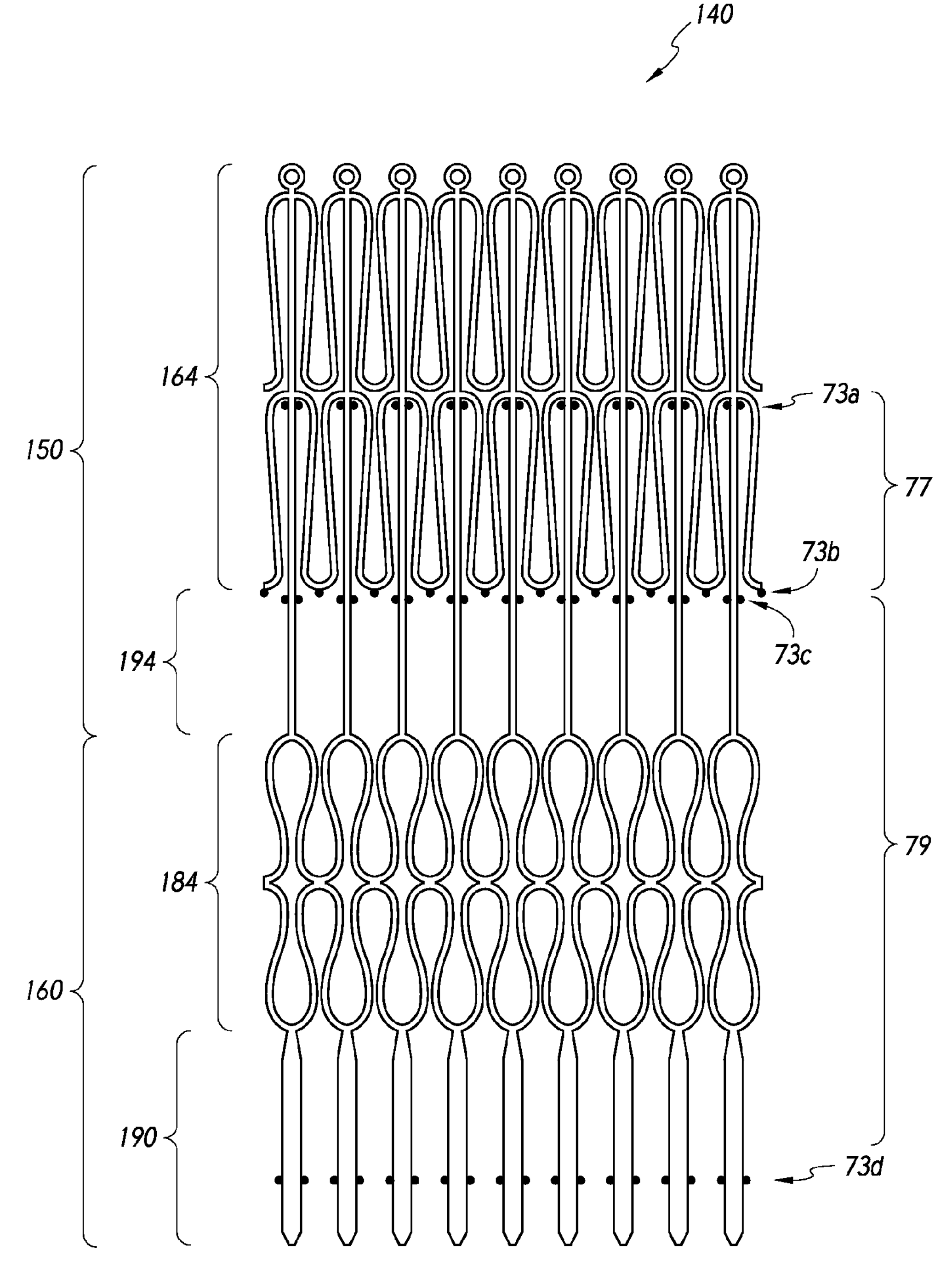


FIG. 5B

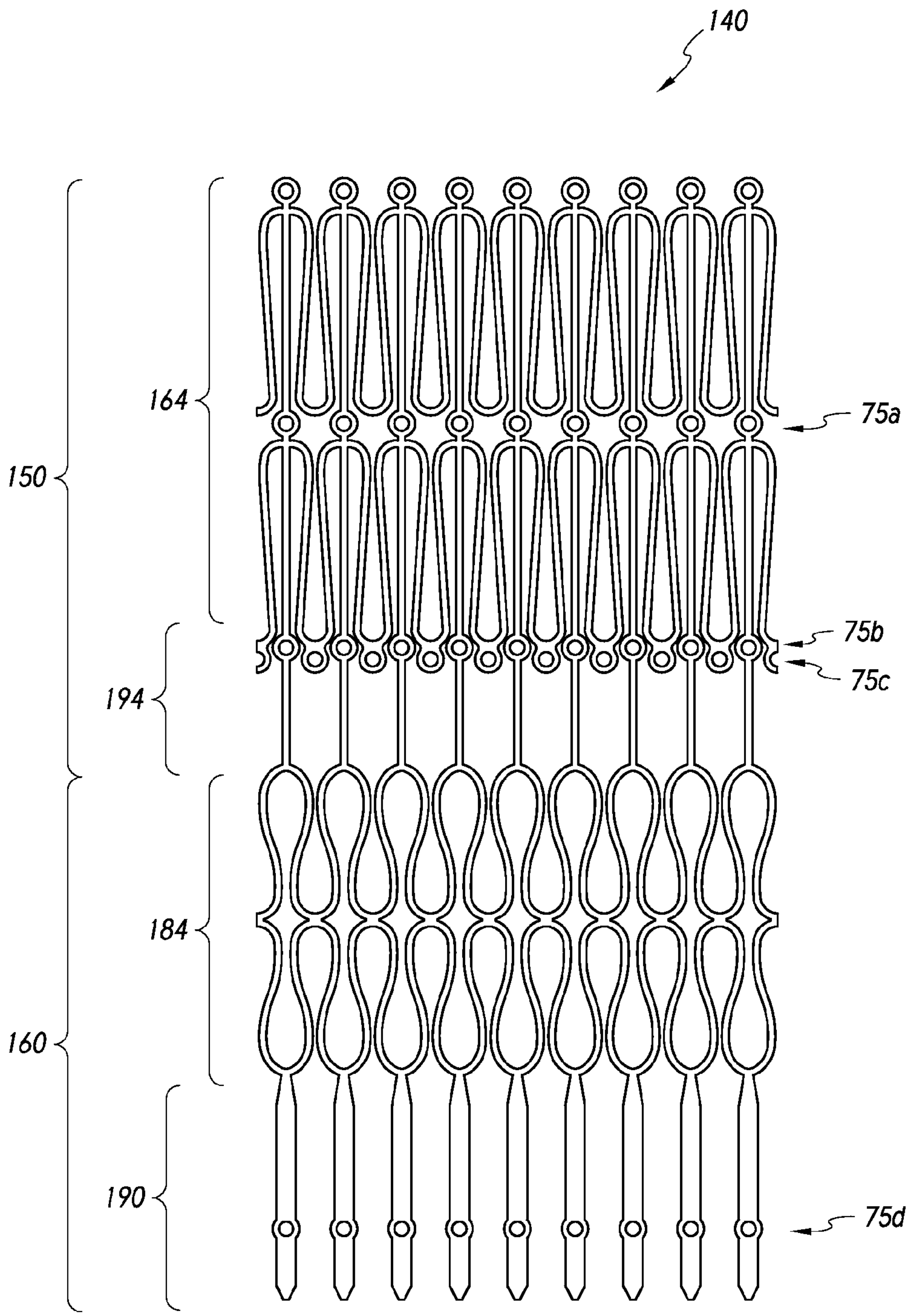


FIG. 5C

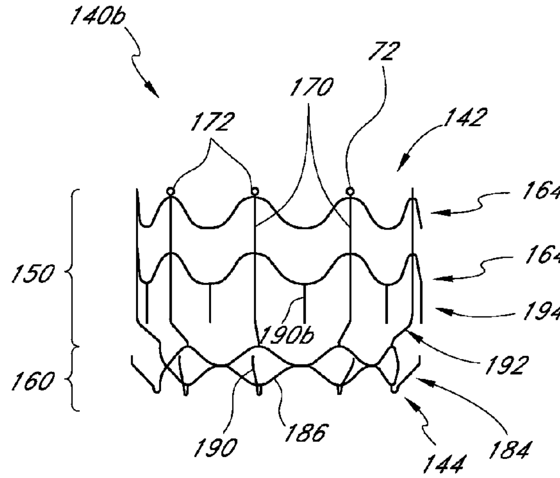


FIG. 7A

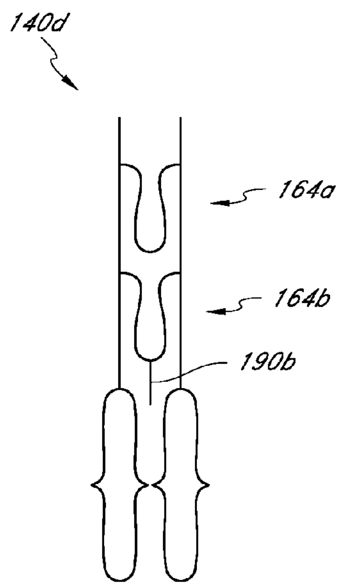


FIG. 7C

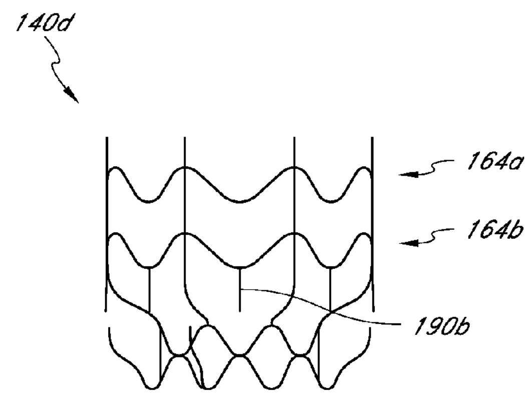


FIG. 7B

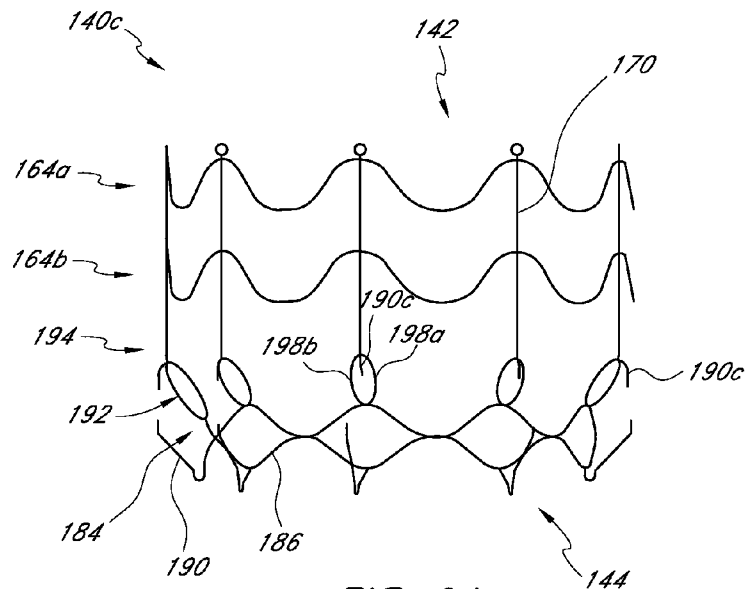


FIG. 8A

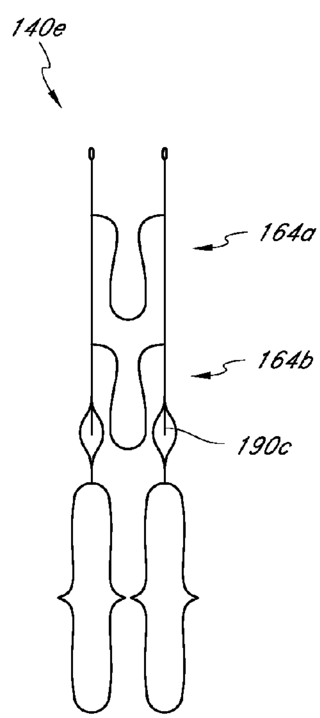


FIG. 8C

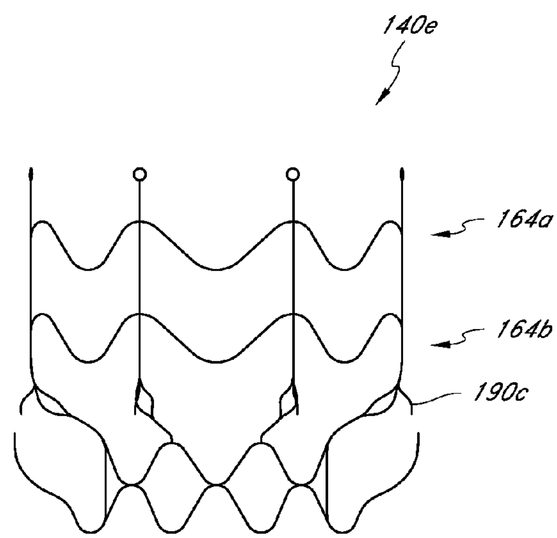


FIG. 8B

FIG. 9A

FIG. 9B

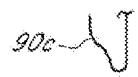


FIG. 9C

FIG. 9D

FIG. 9E

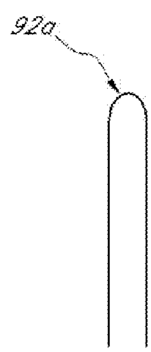


FIG. 10A

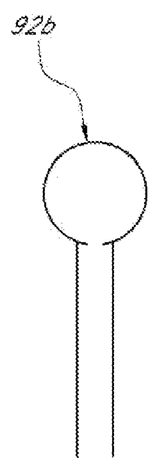


FIG. 10B

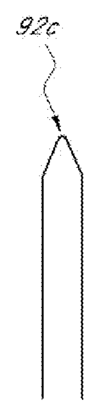


FIG. 10C

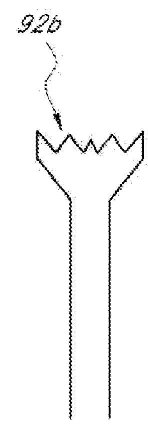


FIG. 10D

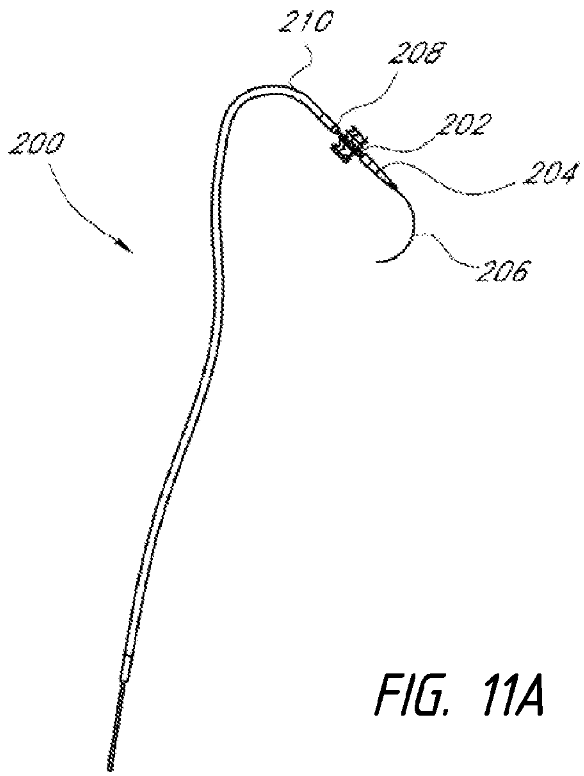


FIG. 11A

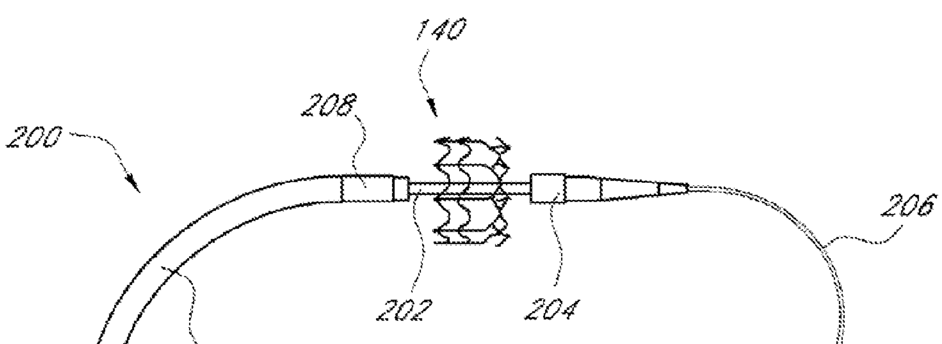


FIG. 11B

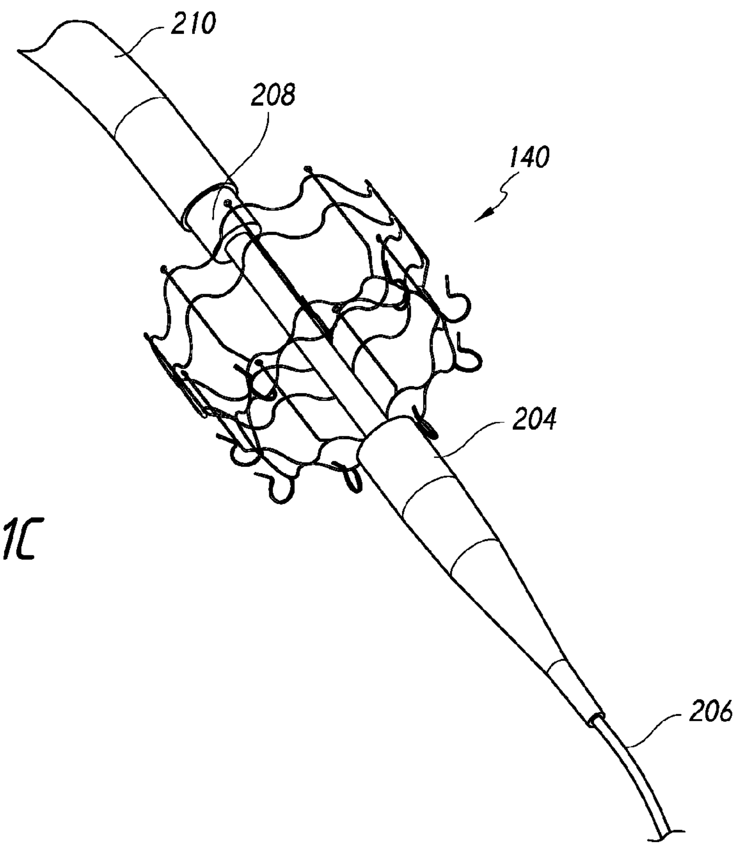


FIG. 11C

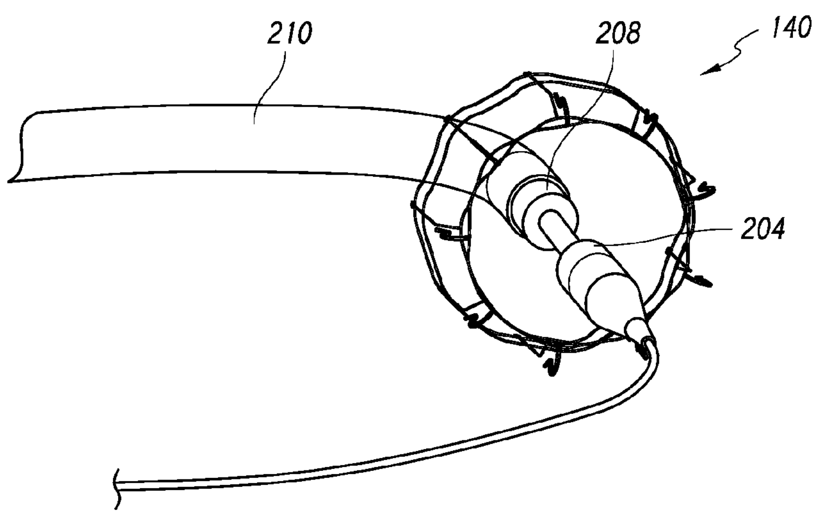


FIG. 11D

FIG. 12A

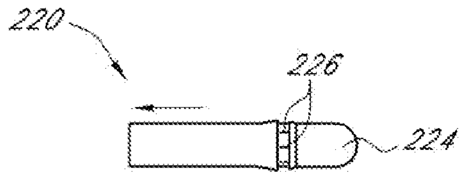


FIG. 12B

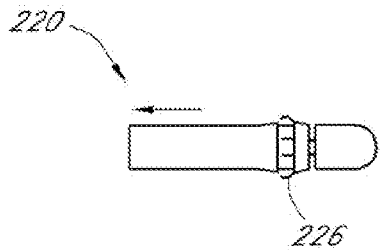


FIG. 12C

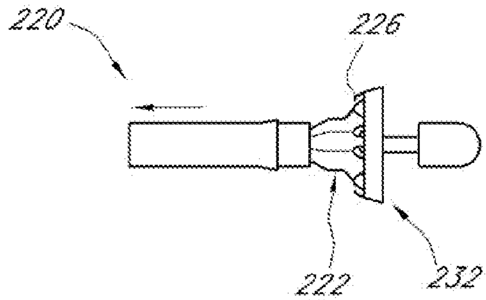


FIG. 12D

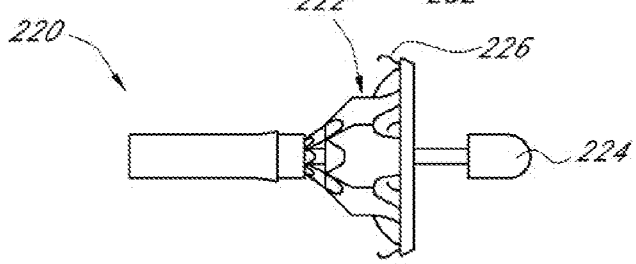


FIG. 12E

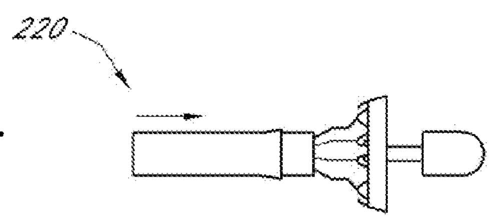
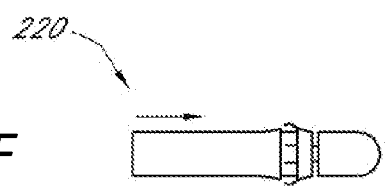


FIG. 12F



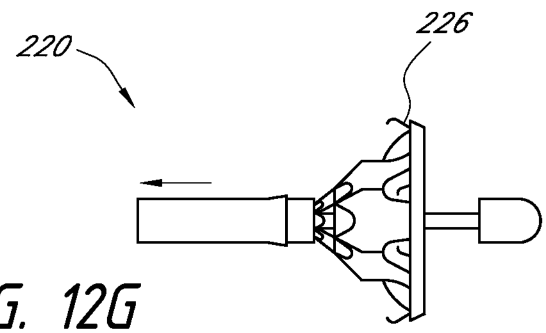


FIG. 12G

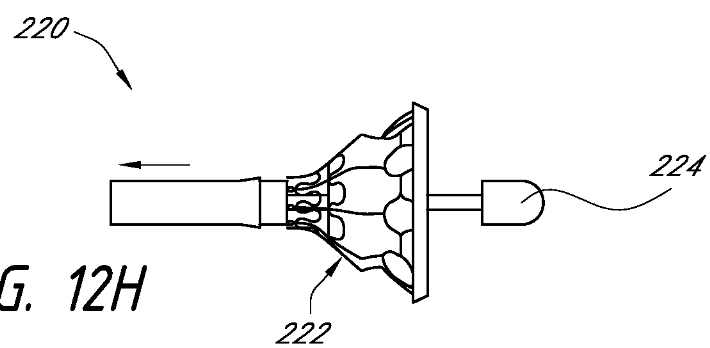


FIG. 12H

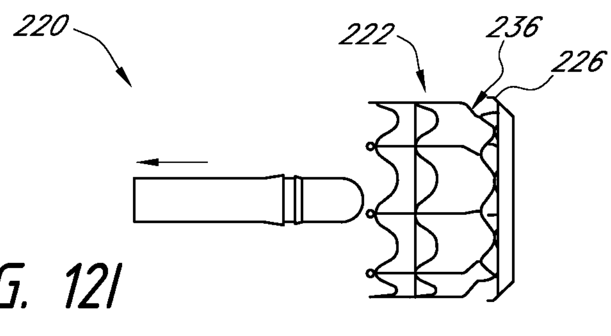


FIG. 12I

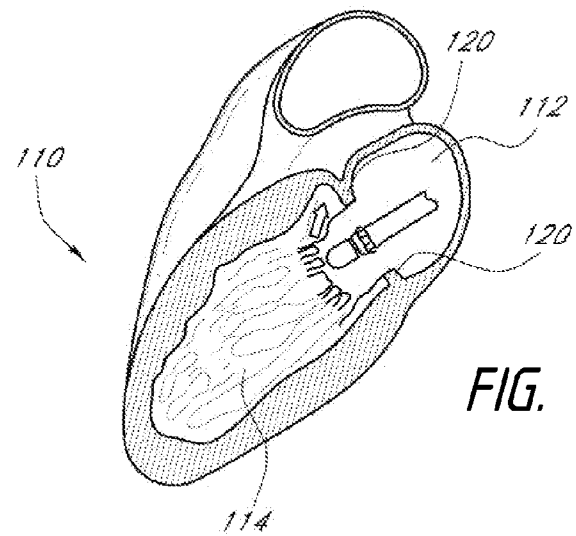


FIG. 13A

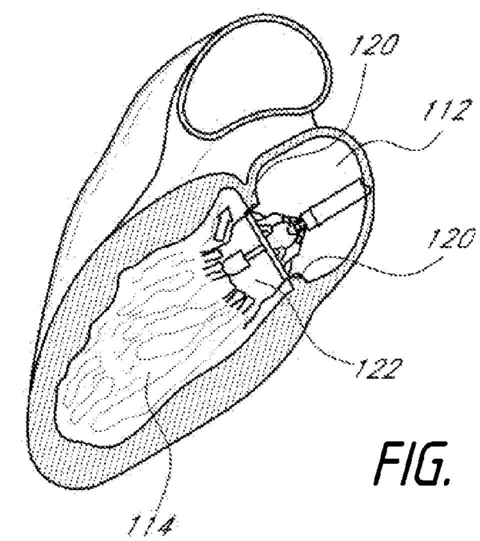


FIG. 13B

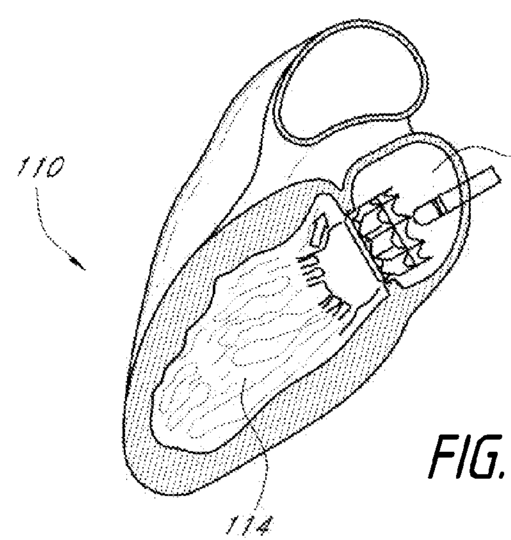


FIG. 13C

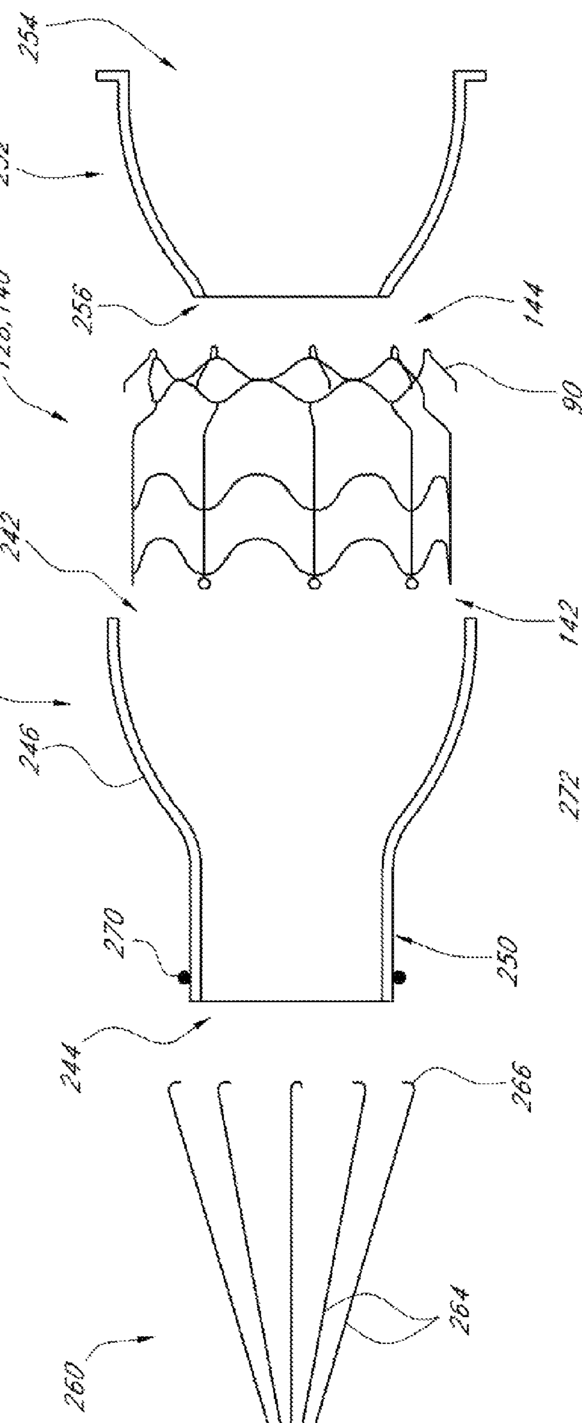


FIG. 14A

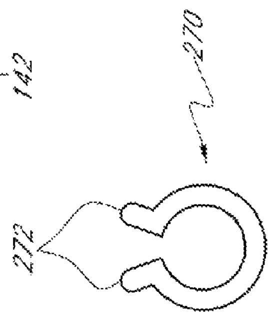


FIG. 14B

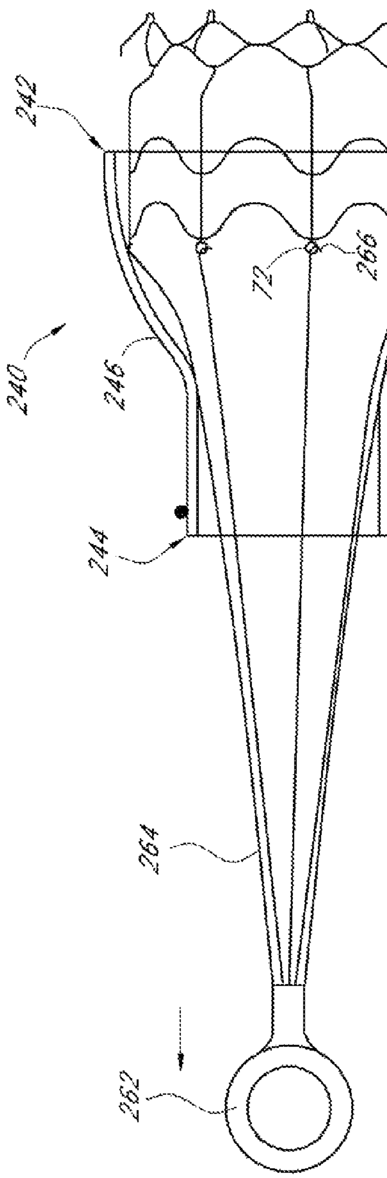


FIG. 14C

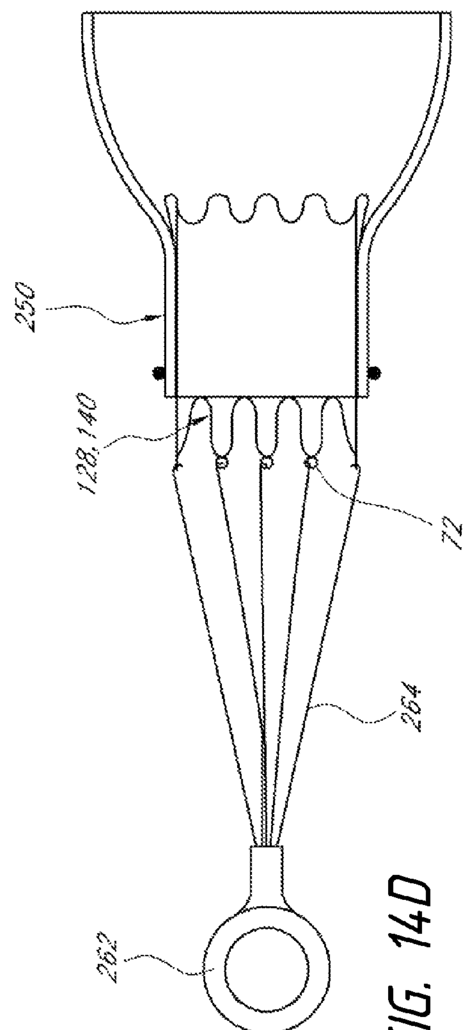


FIG. 14D

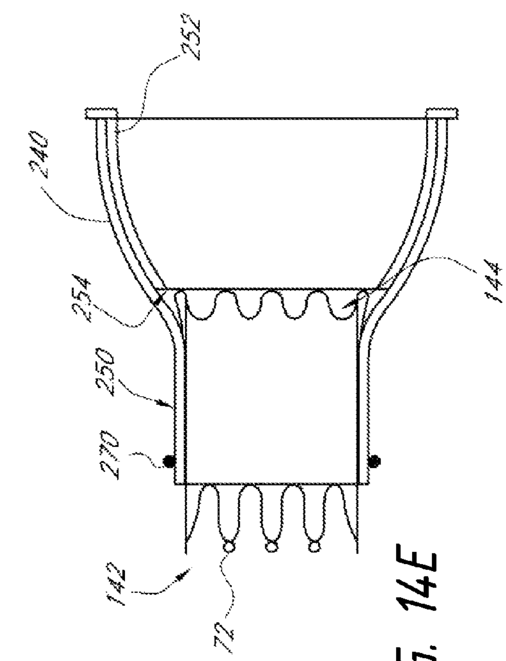


FIG. 14E

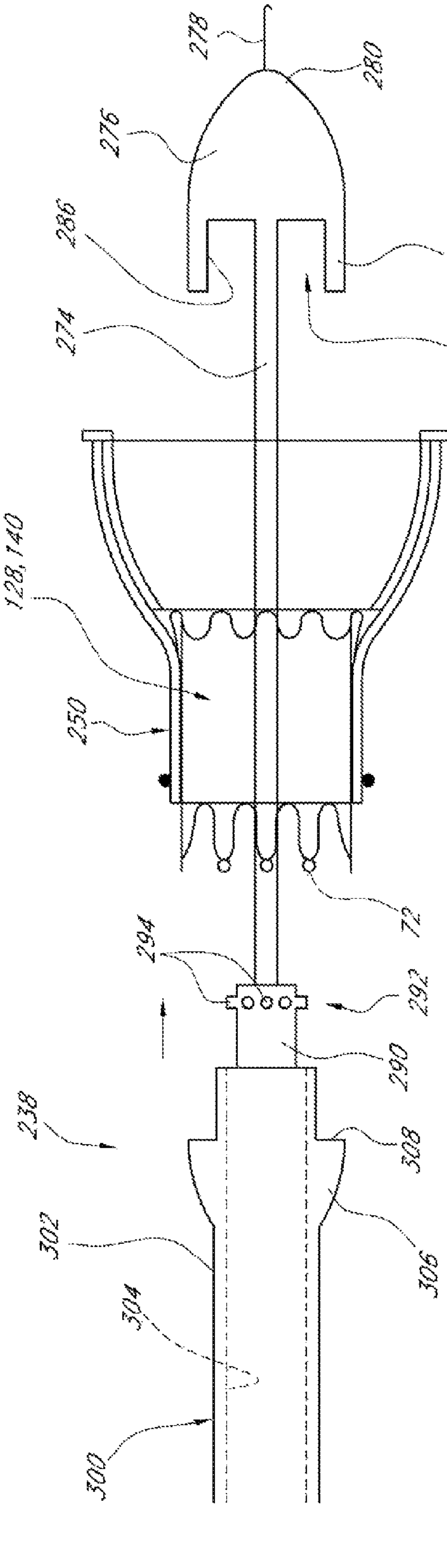


FIG. 14F

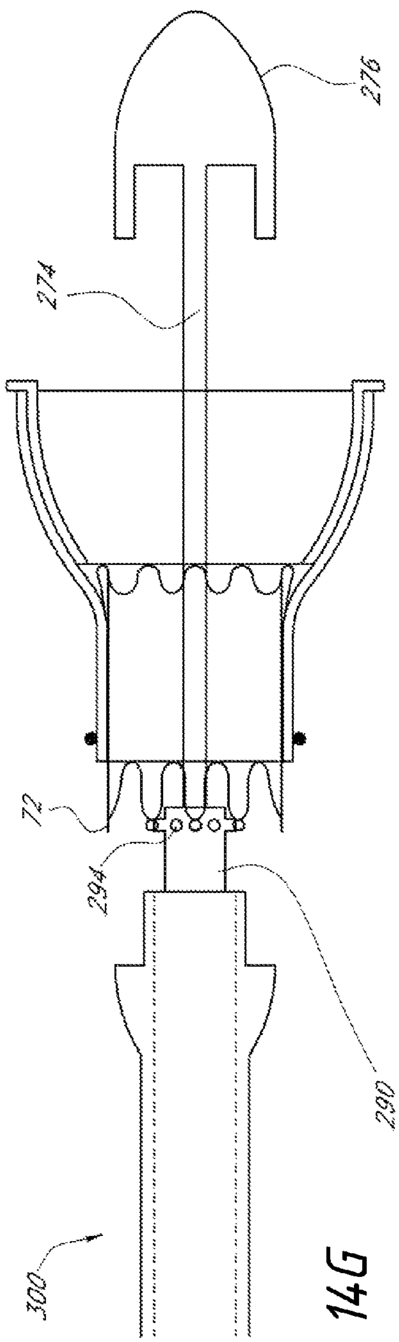


FIG. 14G

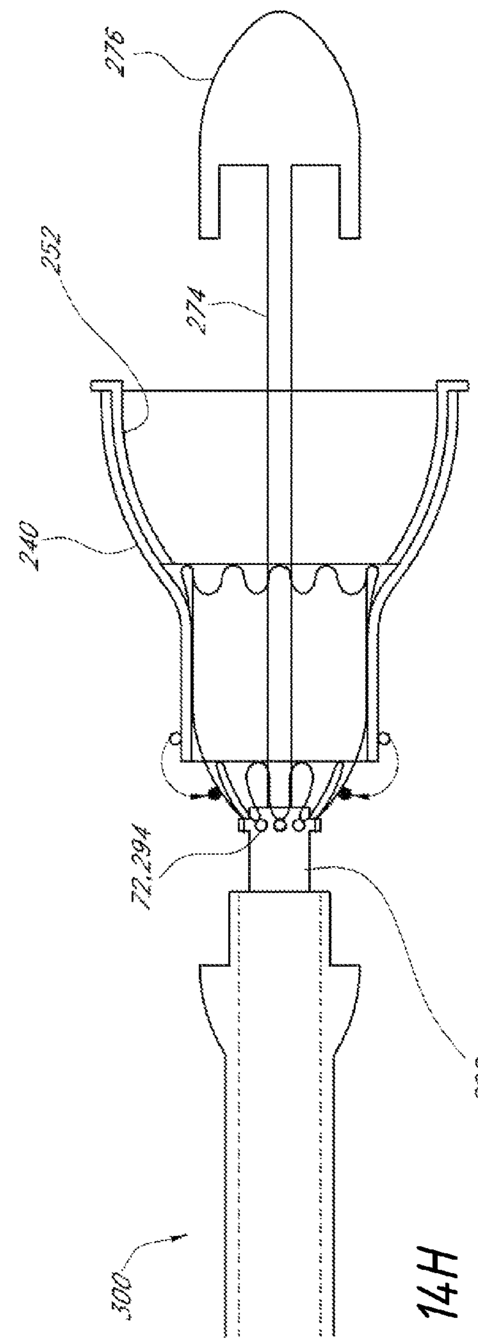


FIG. 14H

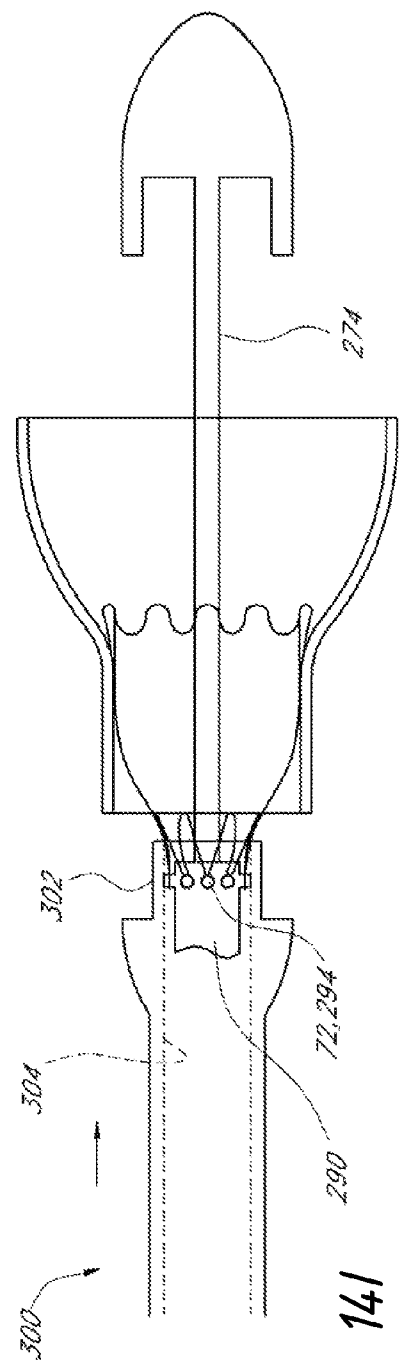


FIG. 14I

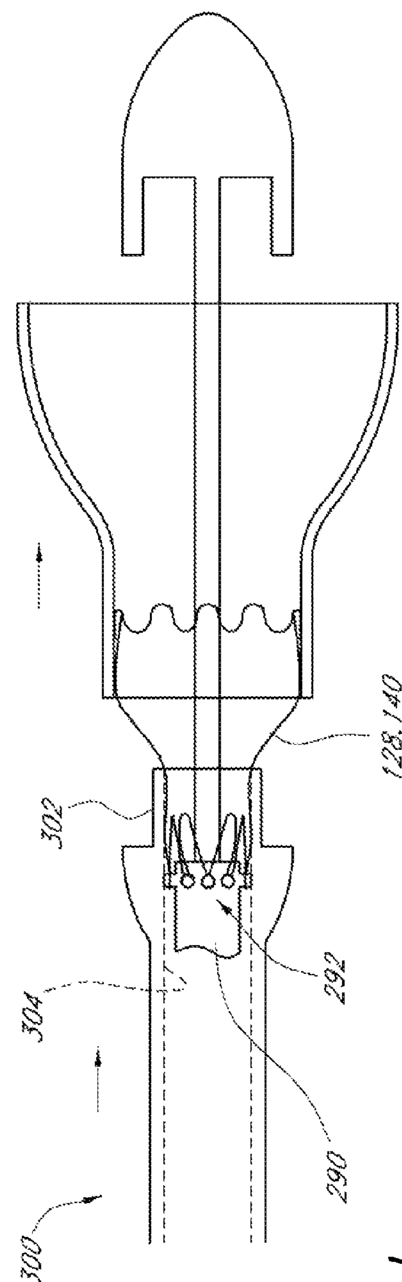


FIG. 14J

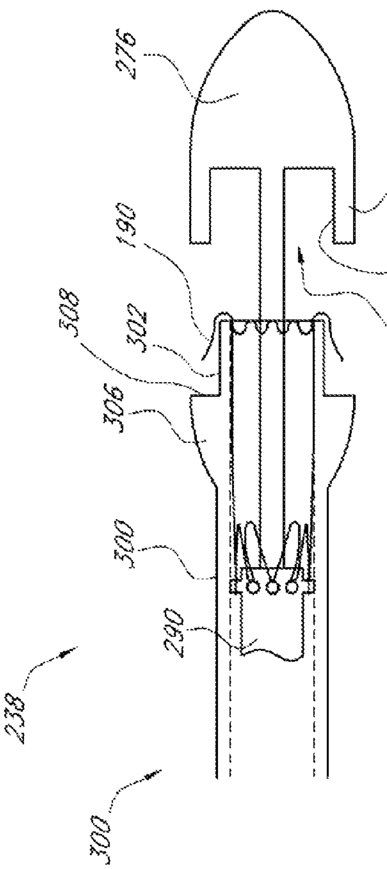


FIG. 14K

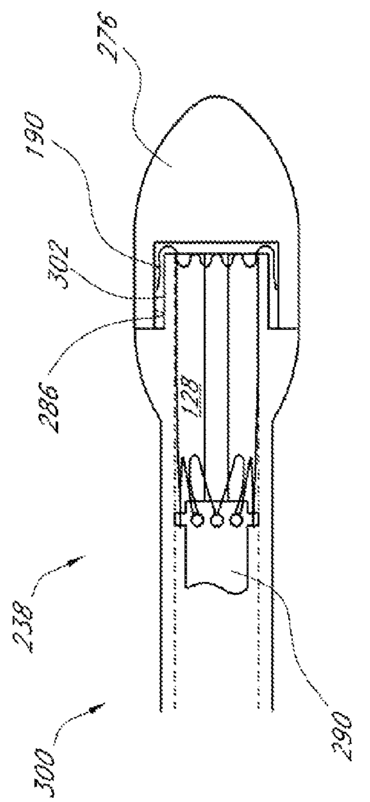


FIG. 14L

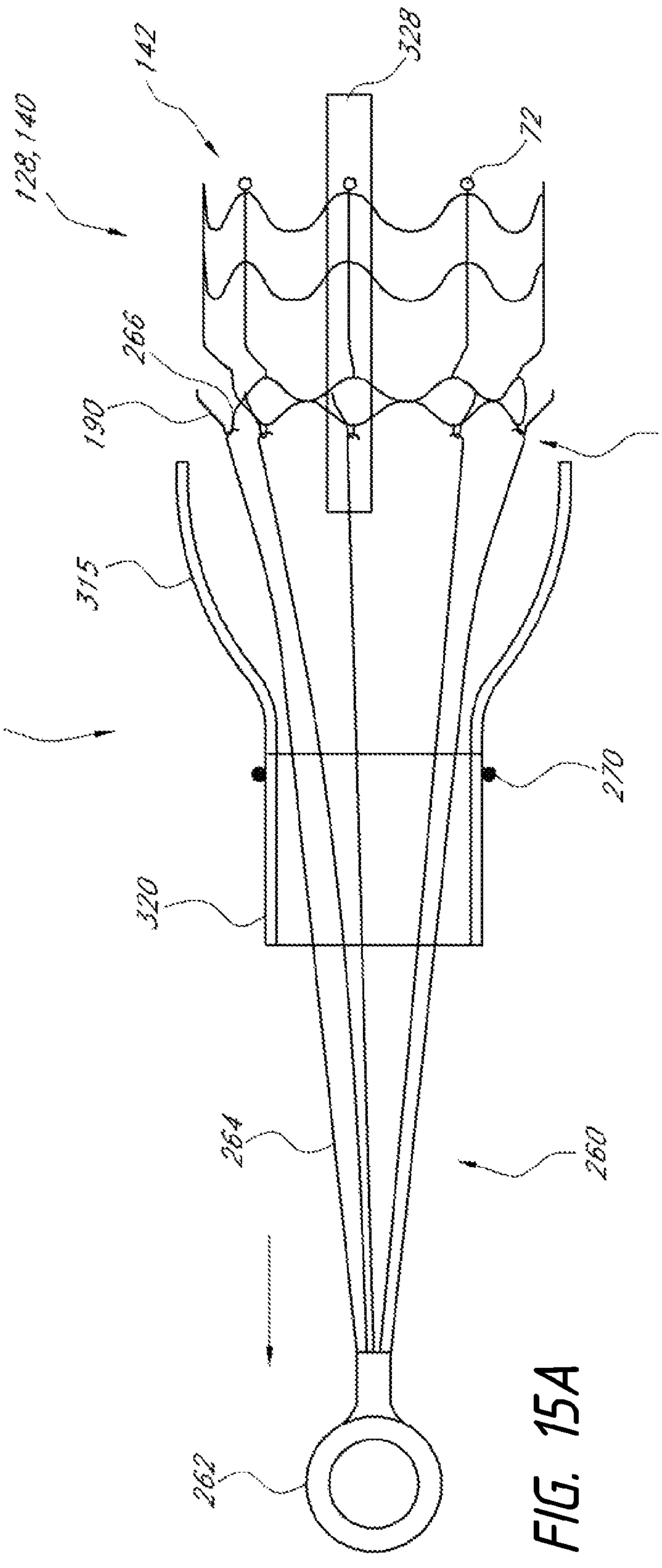


FIG. 15A

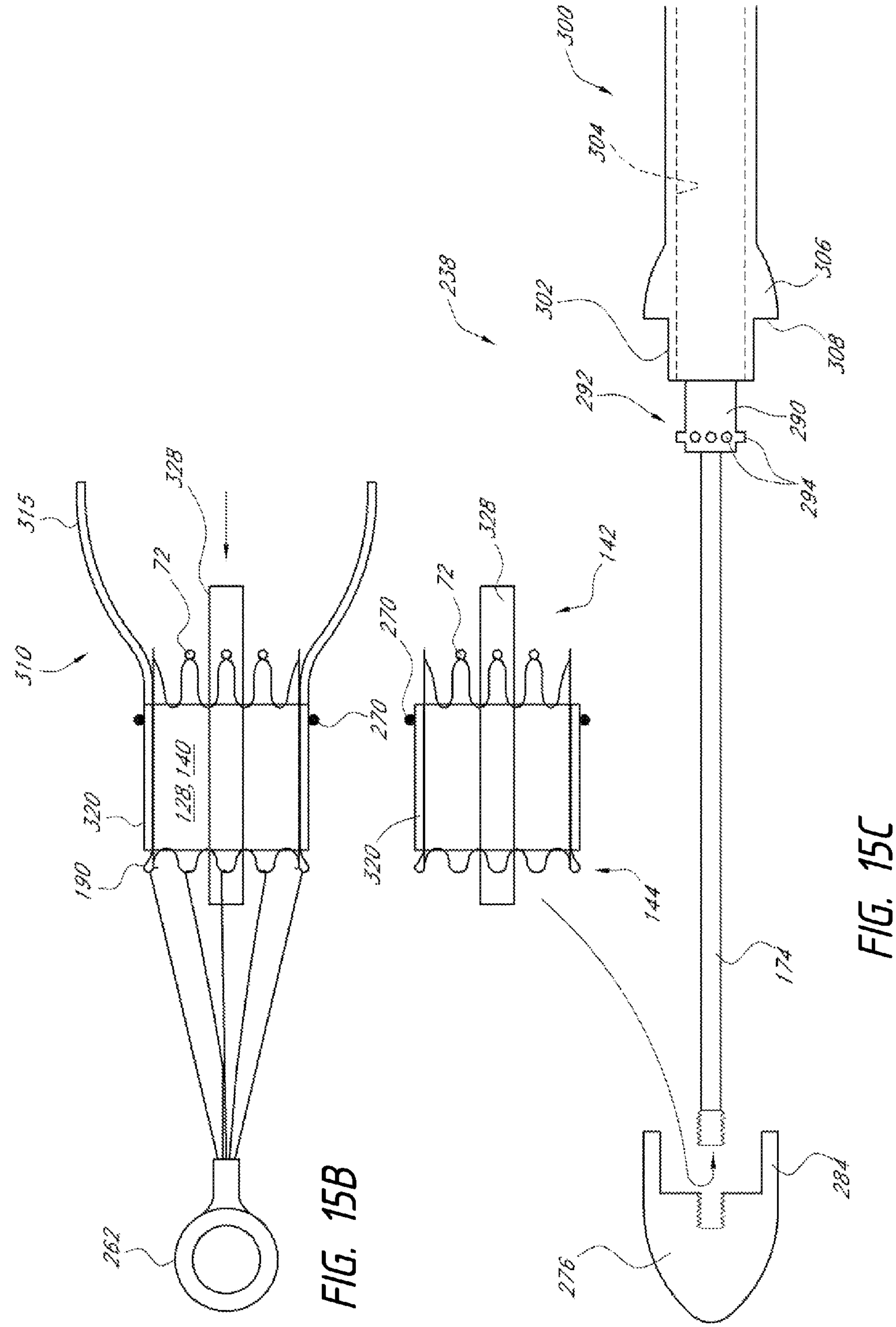


FIG. 15B

FIG. 15C

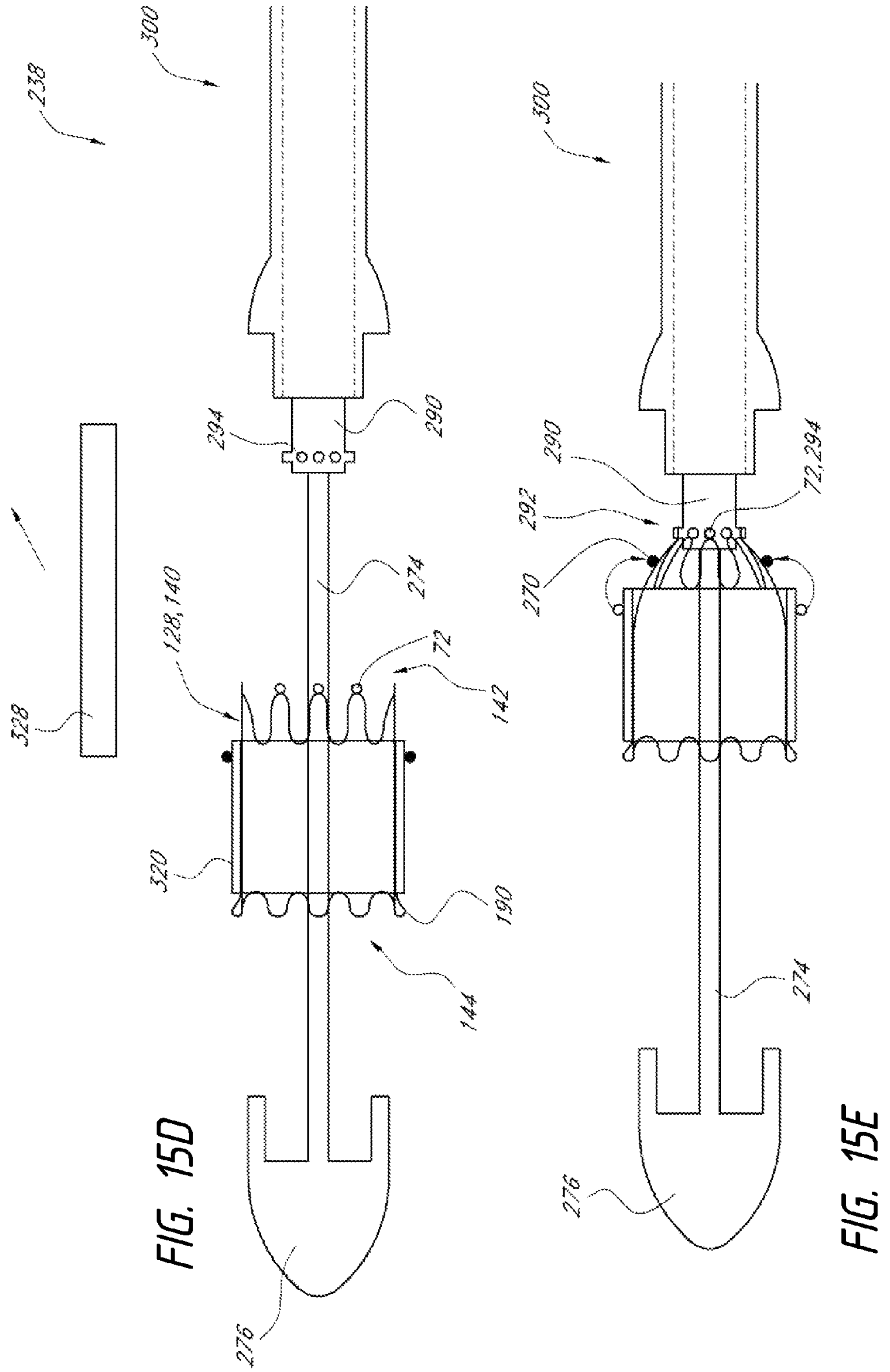


FIG. 15D

FIG. 15E

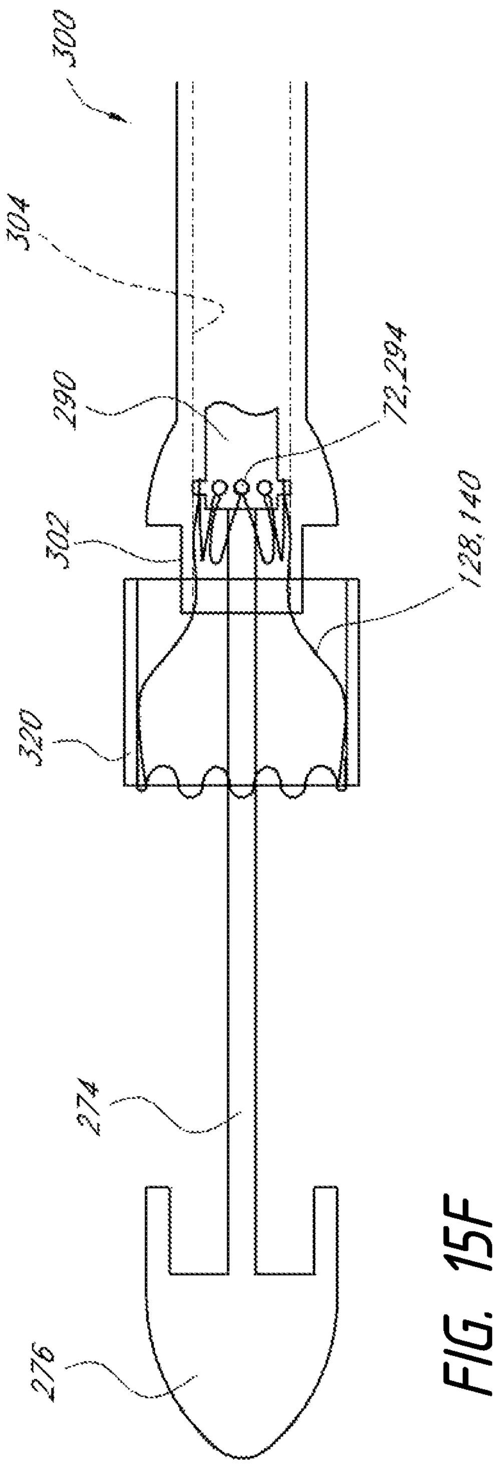


FIG. 15F

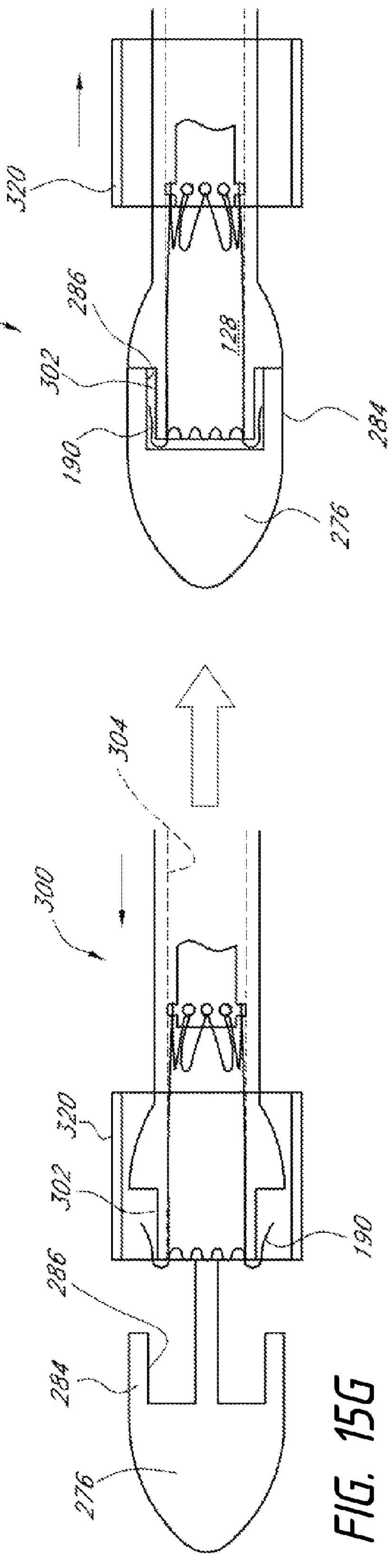


FIG. 15G

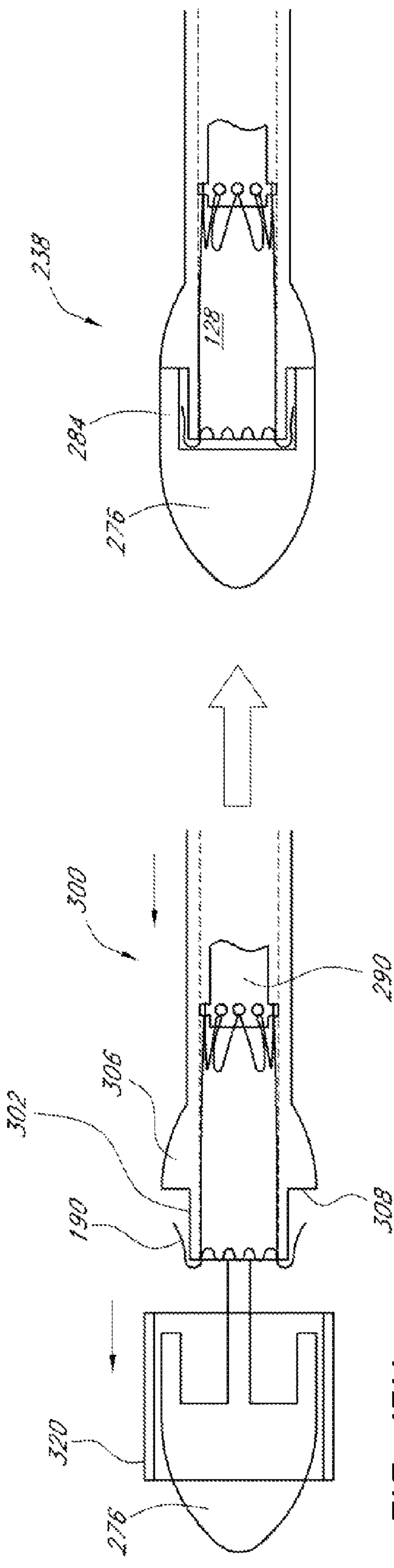


FIG. 15H

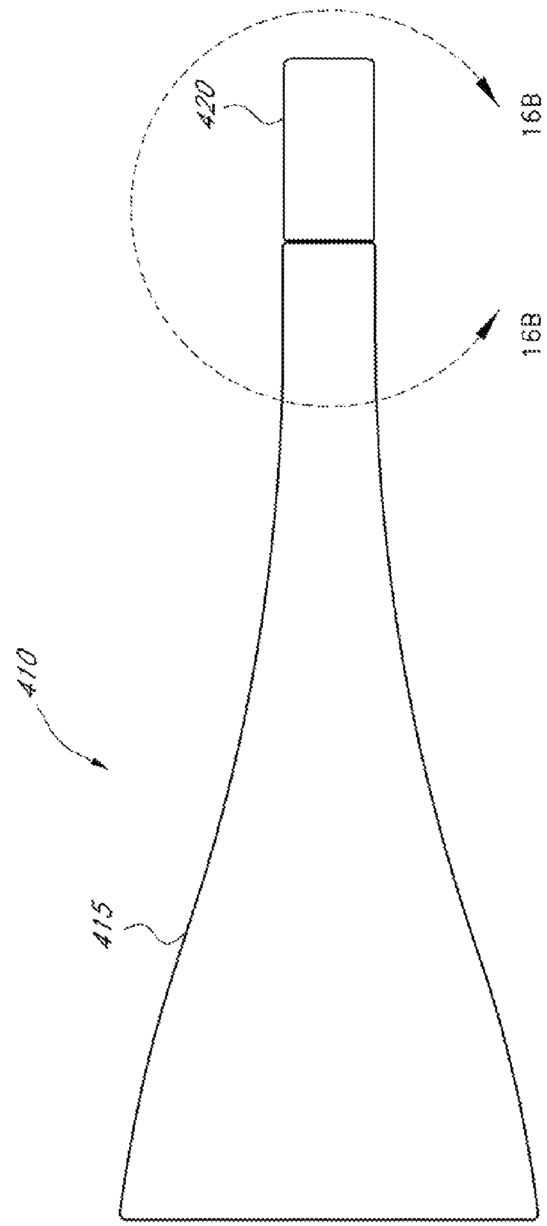


FIG. 16A

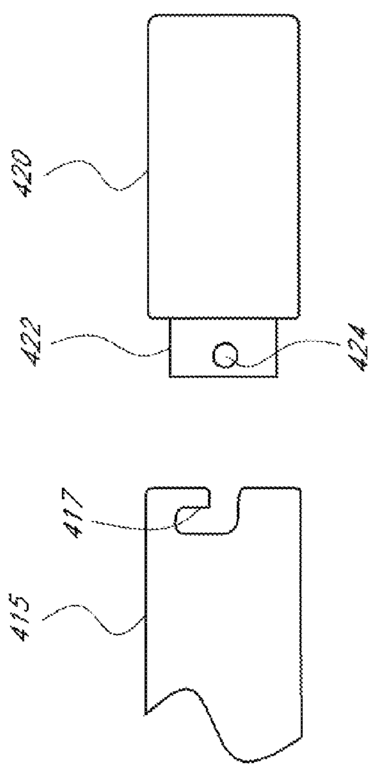


FIG. 16B

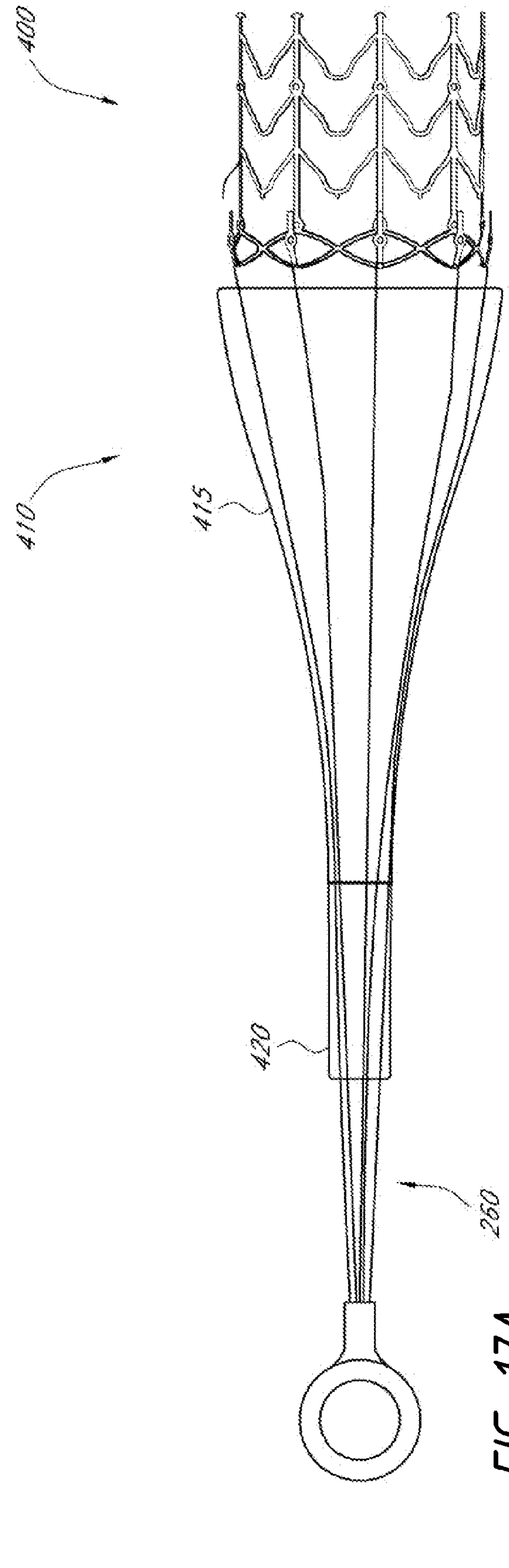


FIG. 17A

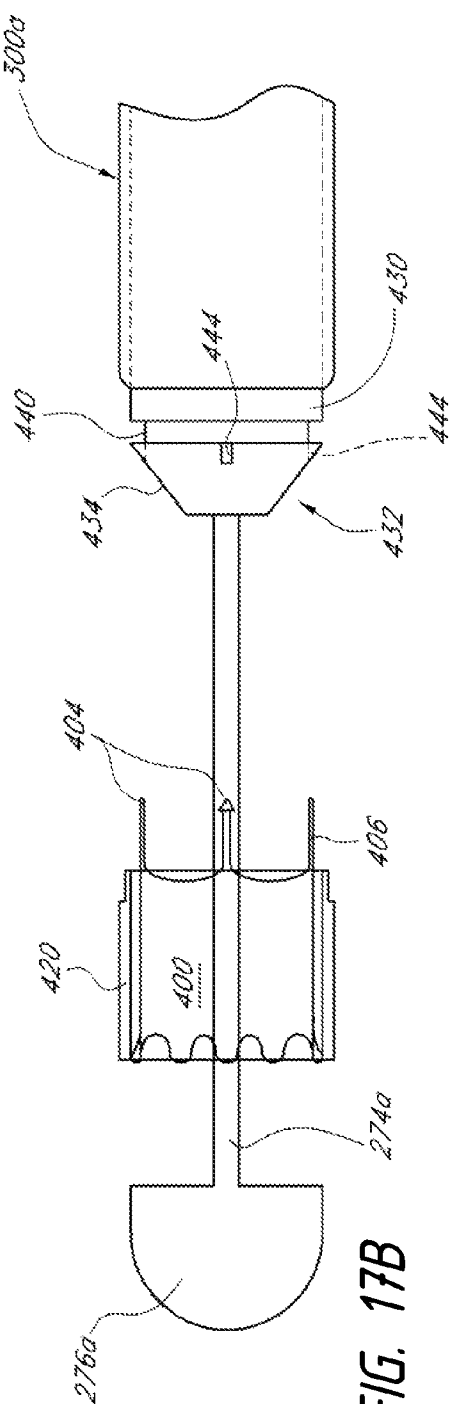


FIG. 17B

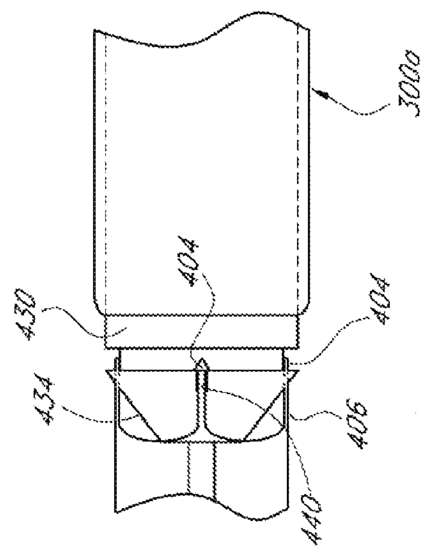


FIG. 17D

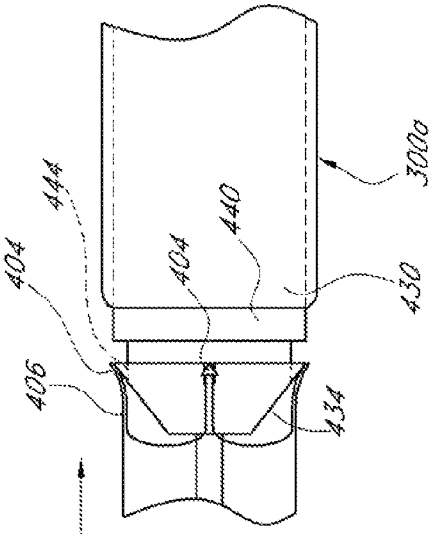


FIG. 17C

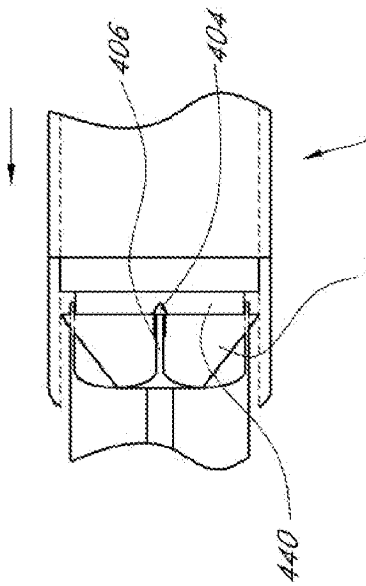


FIG. 17E

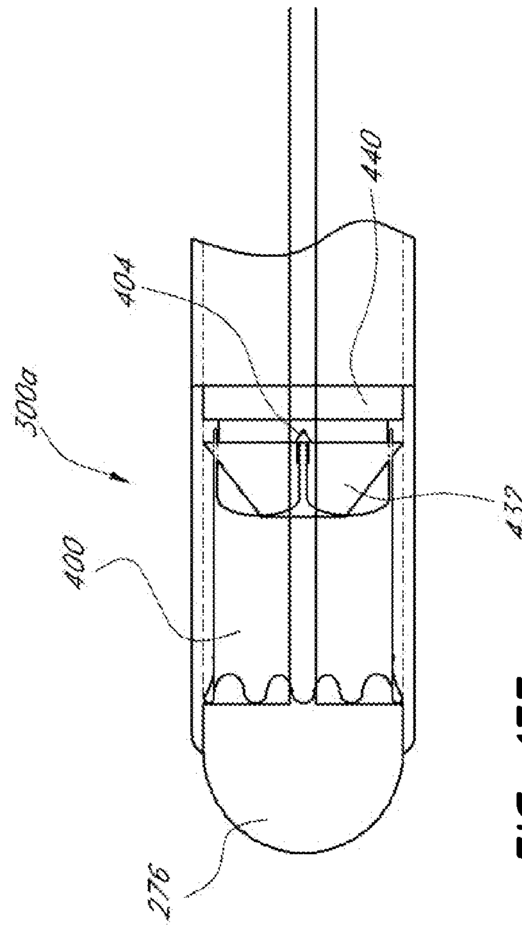


FIG. 17F

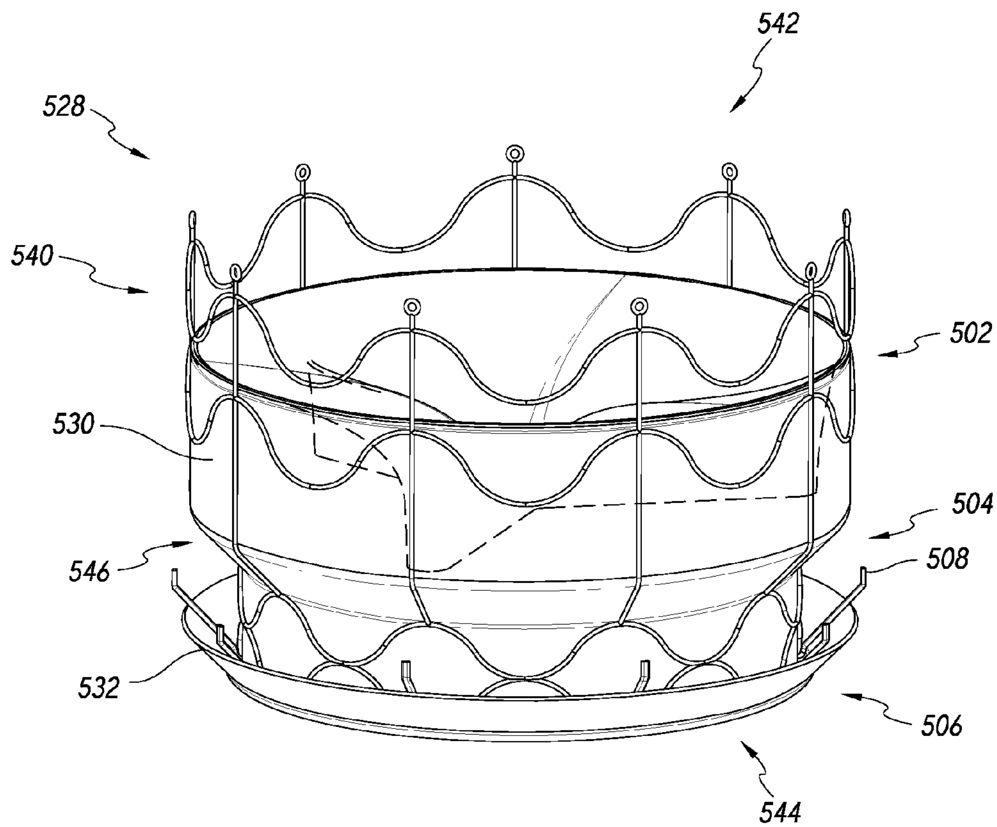


FIG. 18

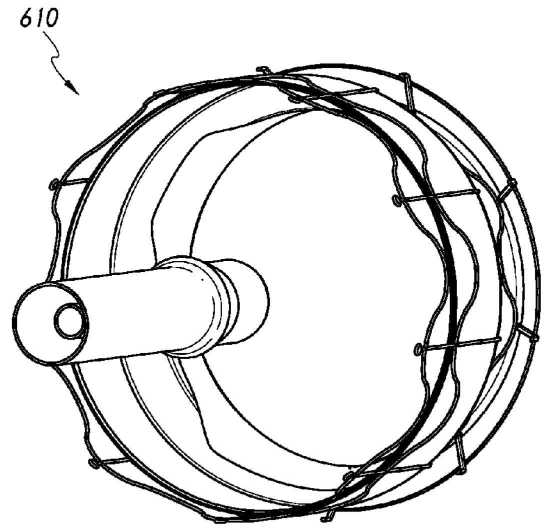


FIG. 19A

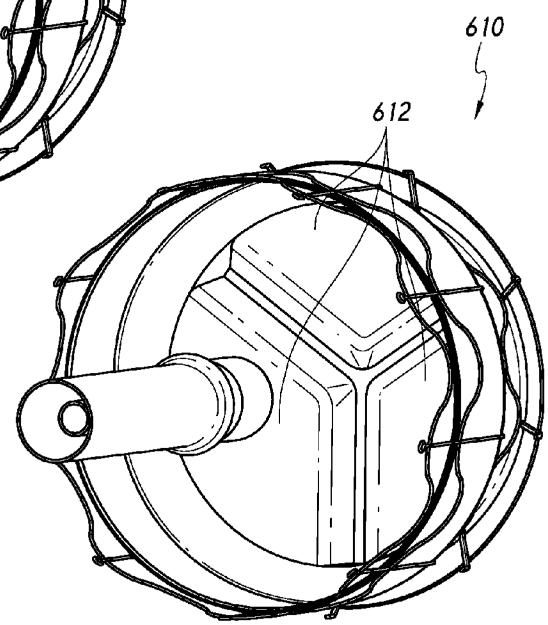


FIG. 19B

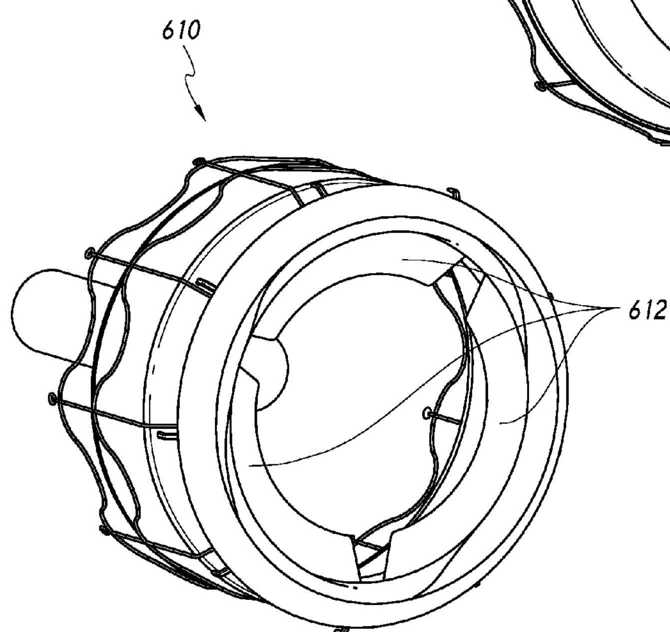


FIG. 19C

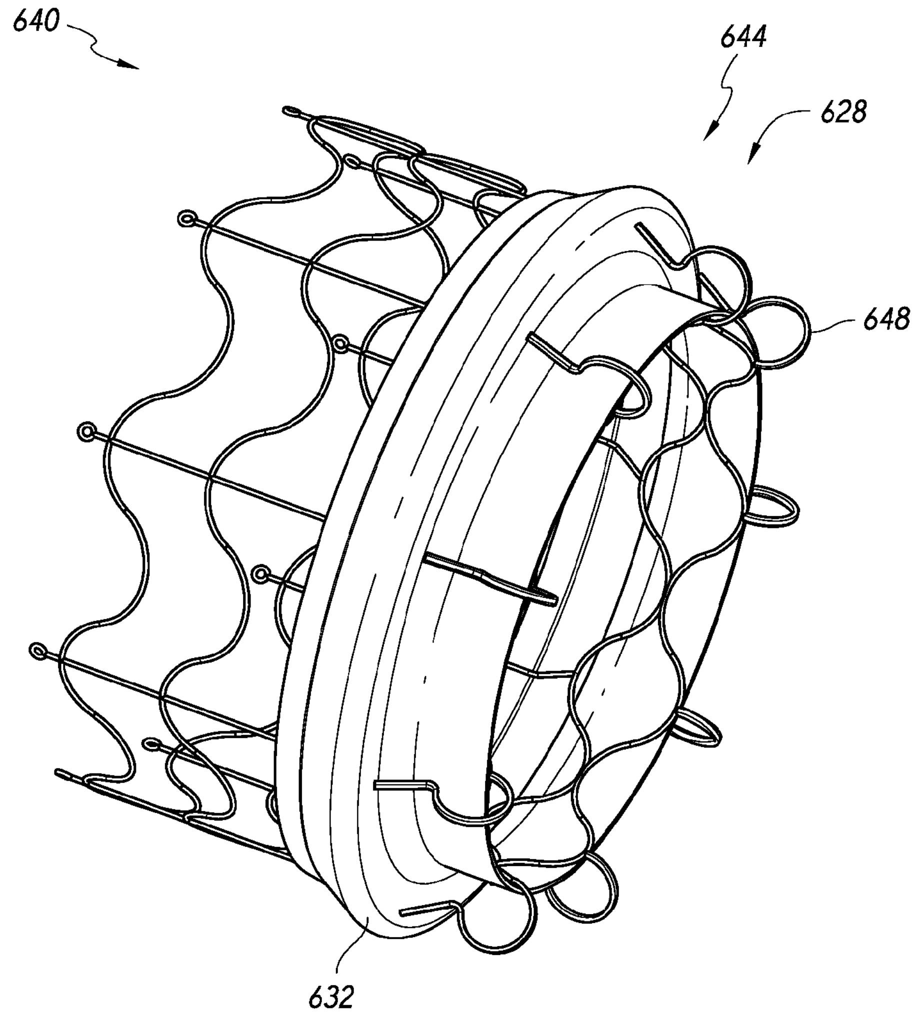


FIG. 20A

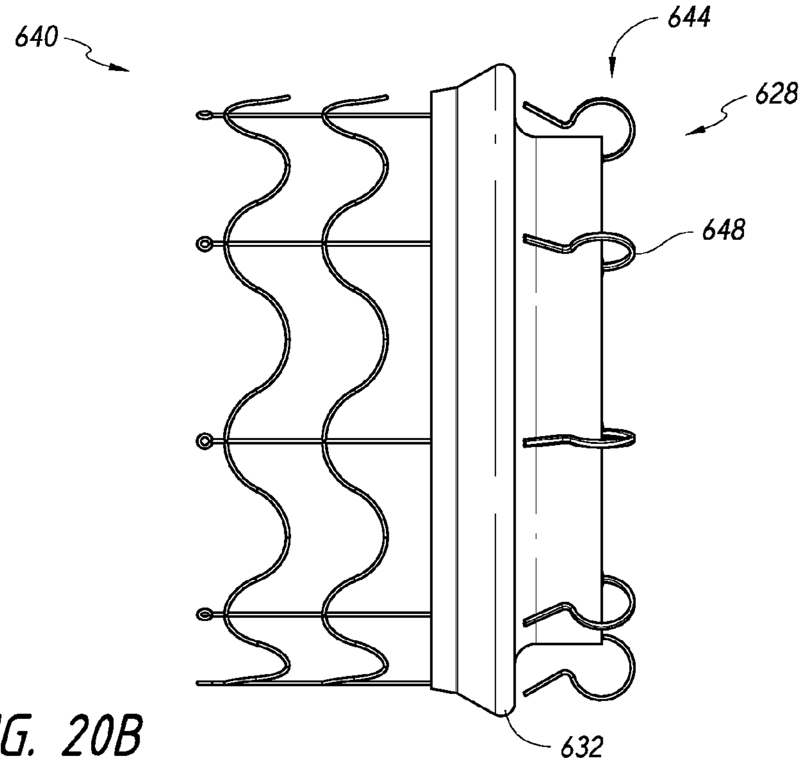


FIG. 20B

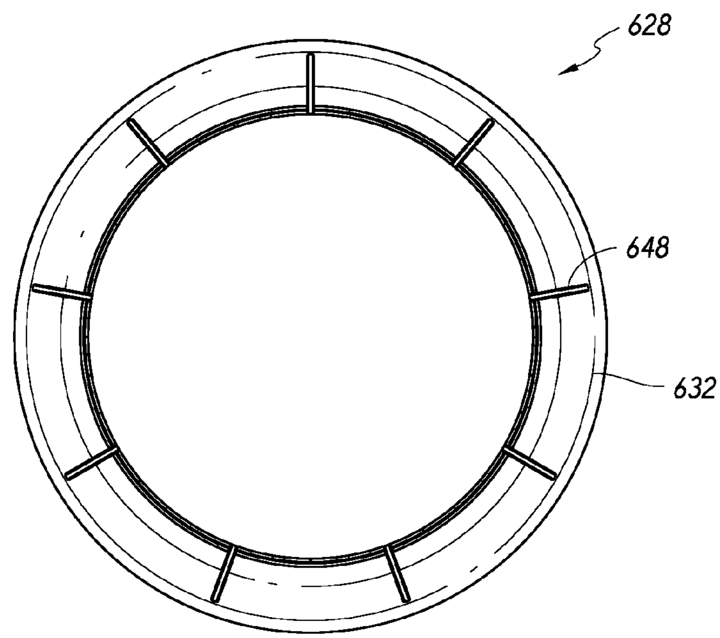


FIG. 20C

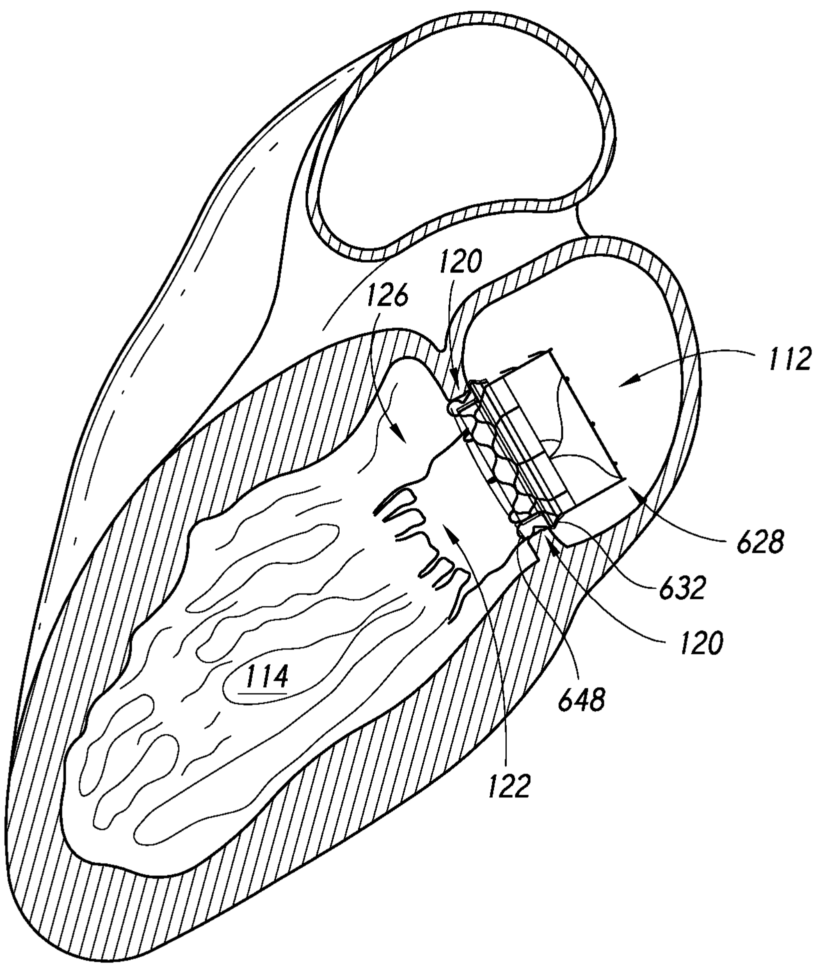


FIG. 21

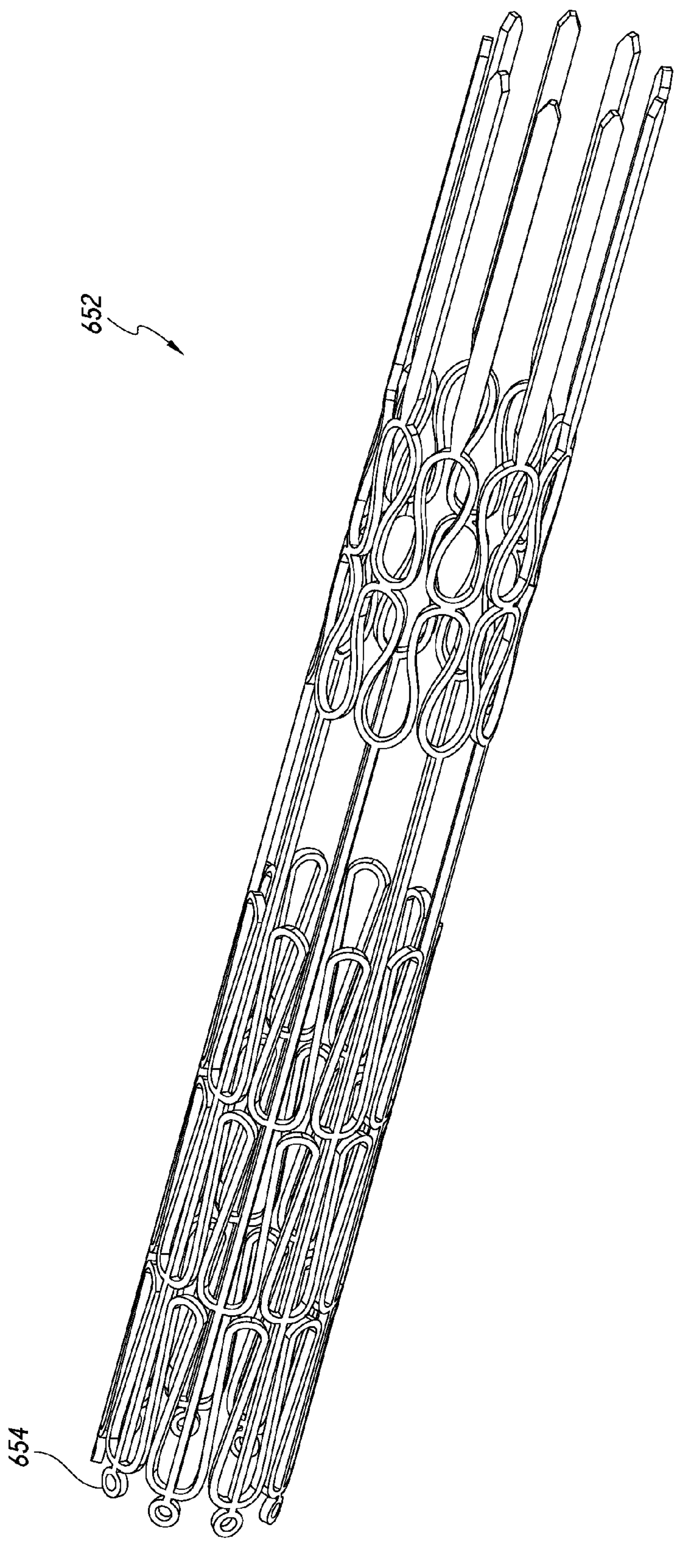


FIG. 22A

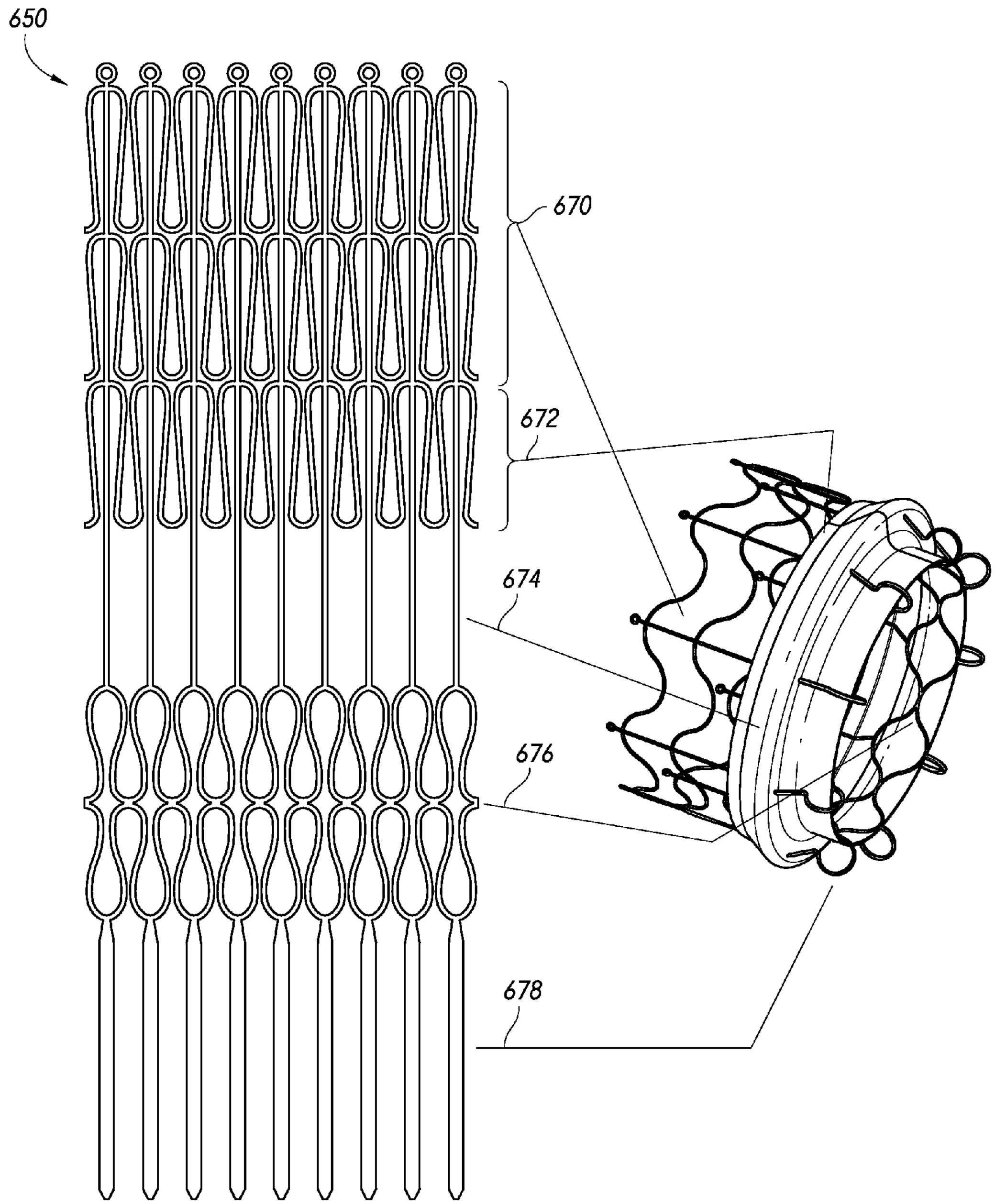


FIG. 22B

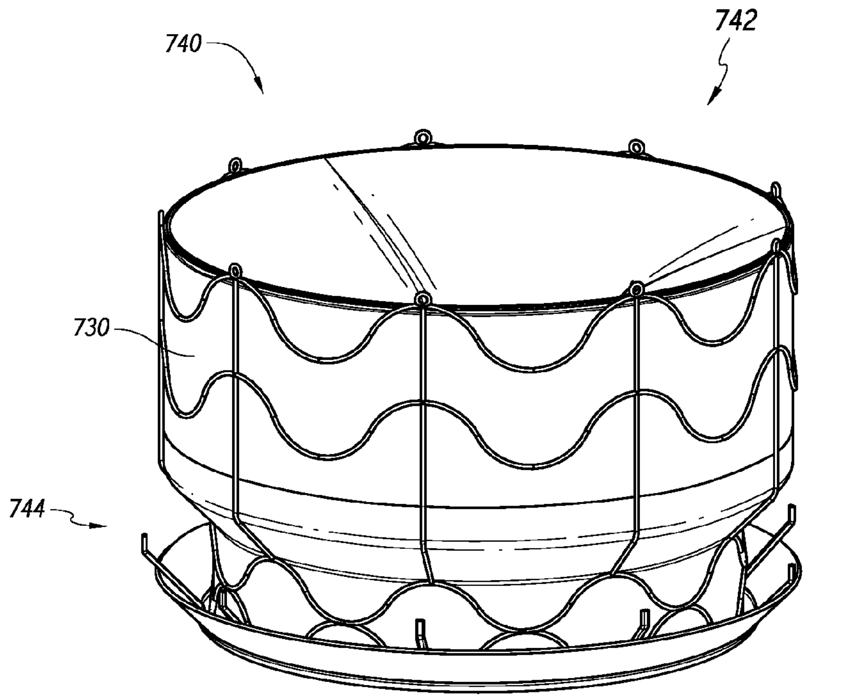


FIG. 23A

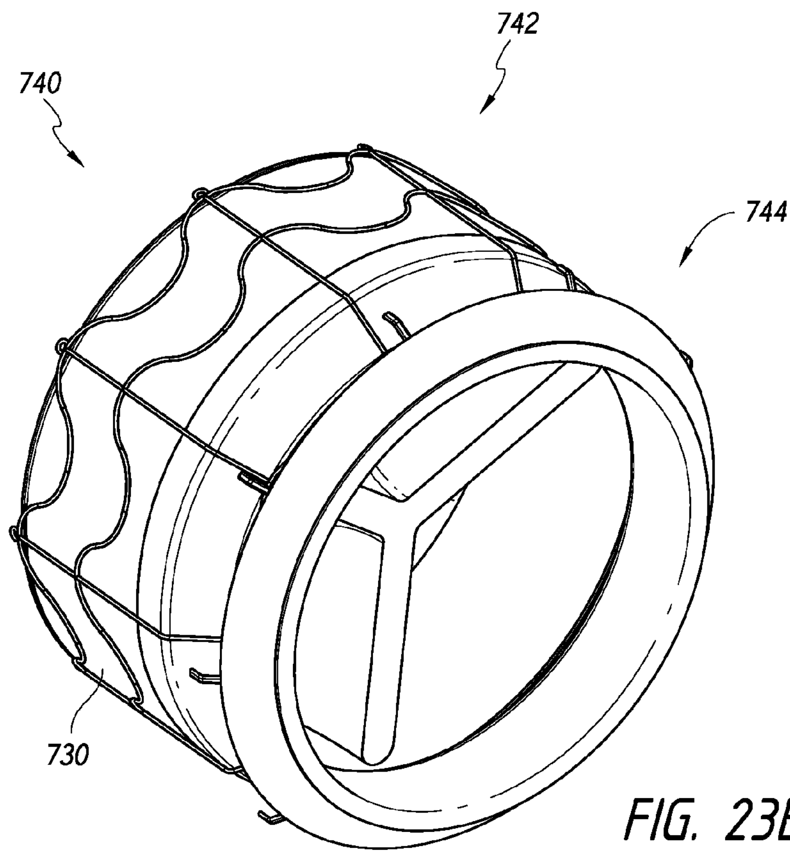


FIG. 23B

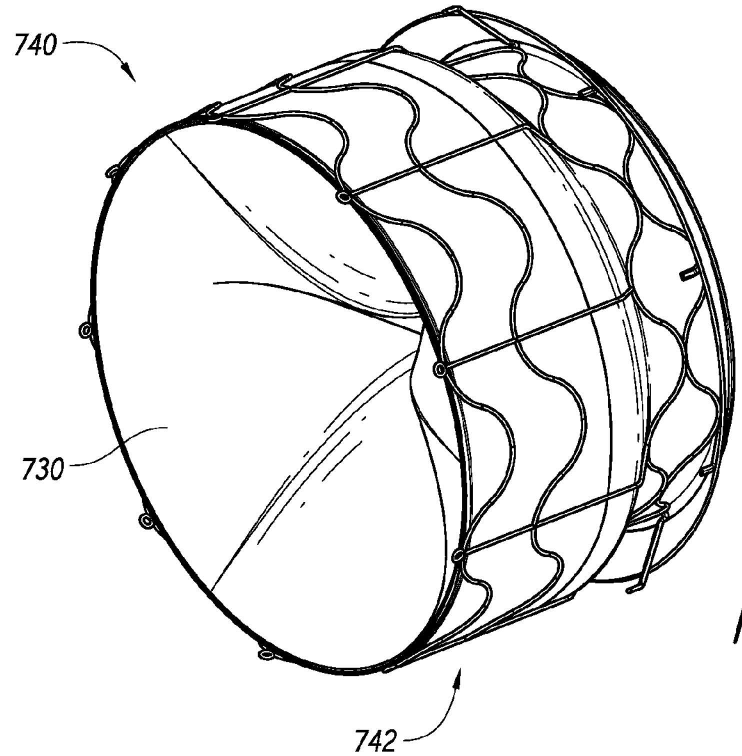


FIG. 23C

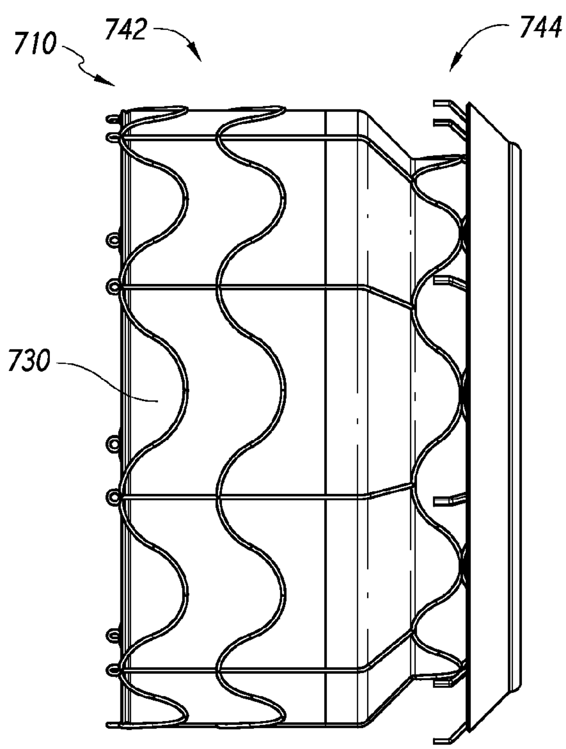


FIG. 23D

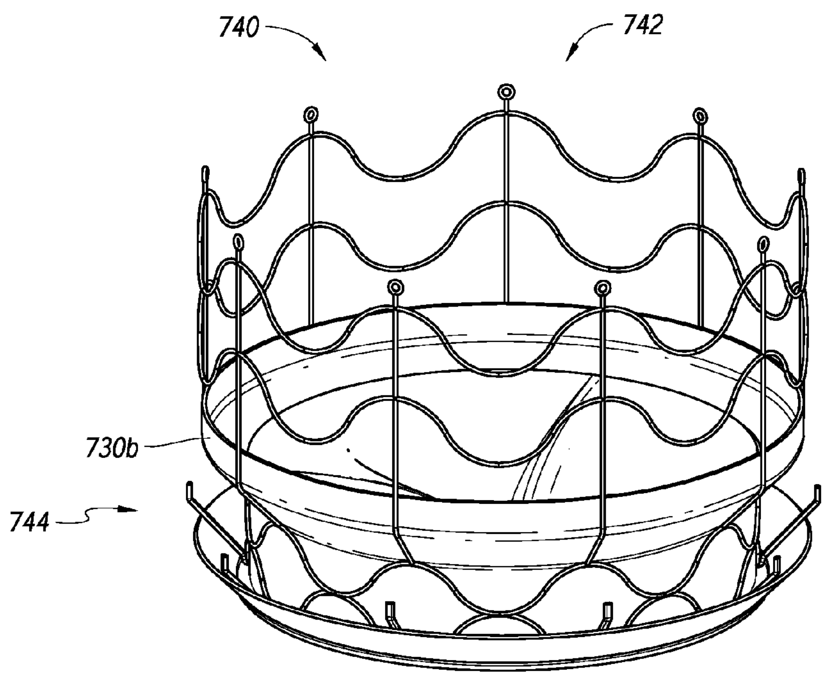


FIG. 24A

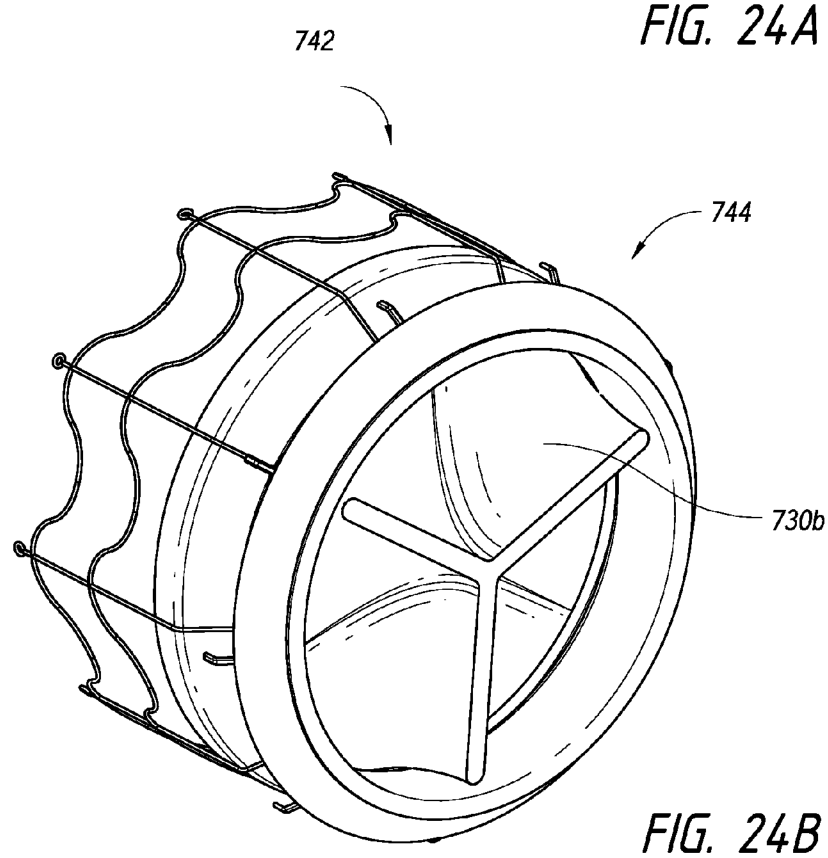


FIG. 24B

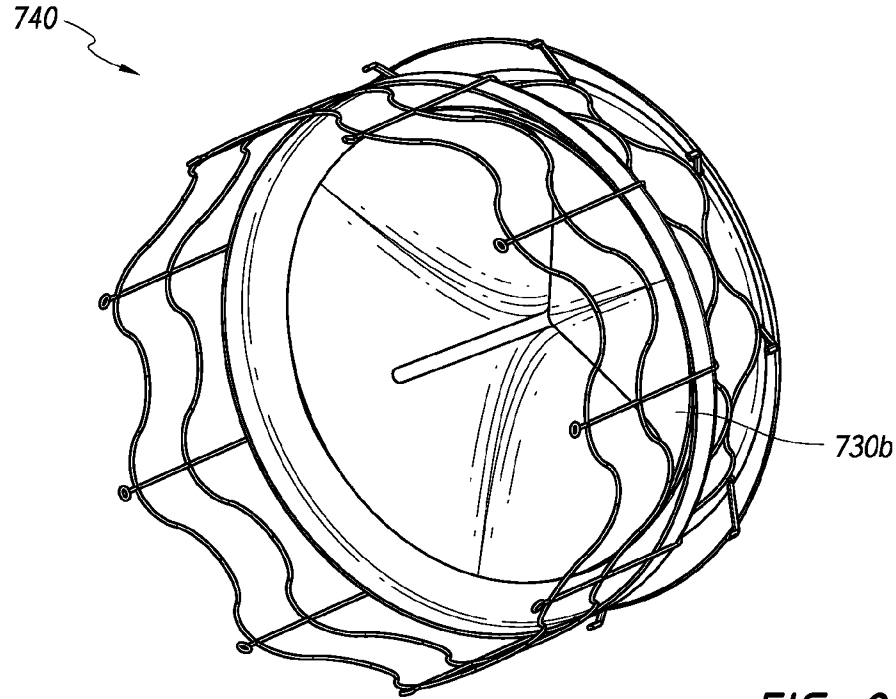


FIG. 24C

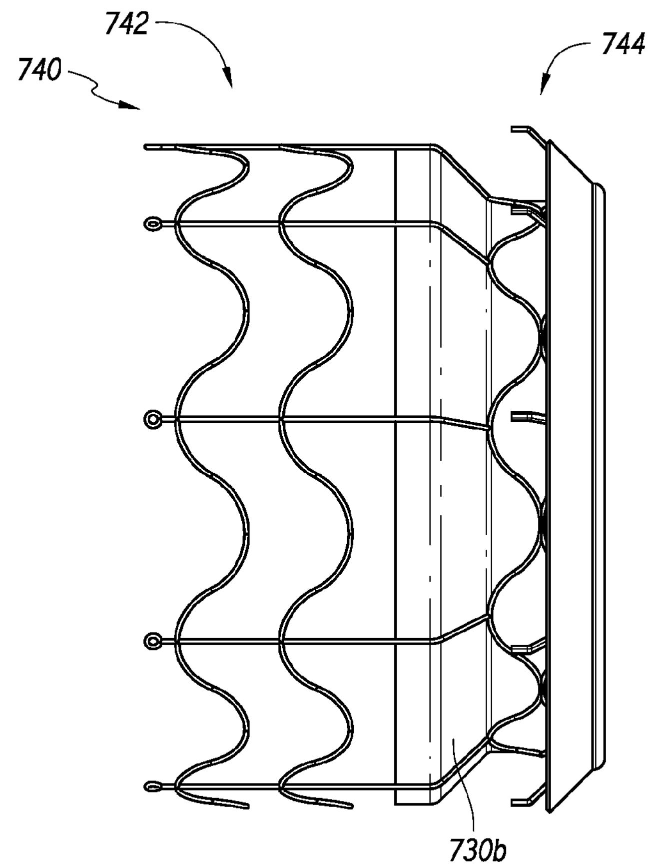


FIG. 24D

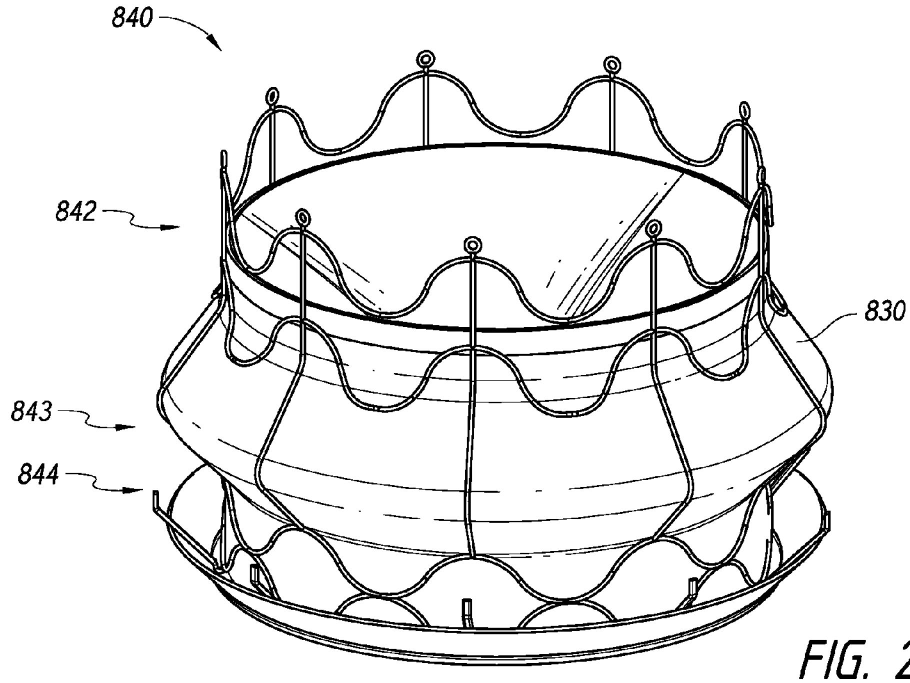


FIG. 25A

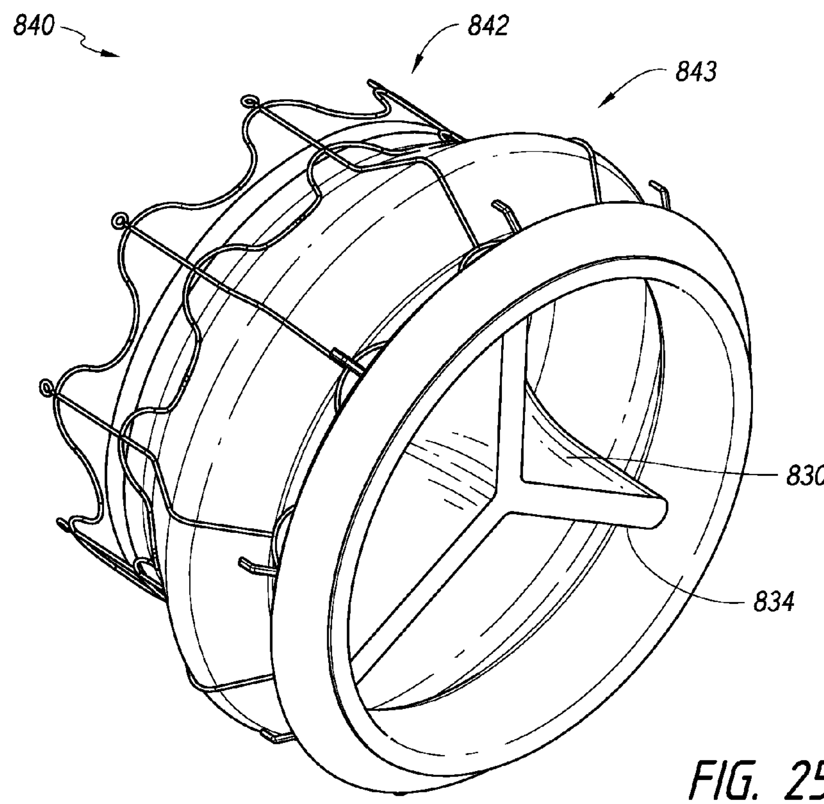


FIG. 25B

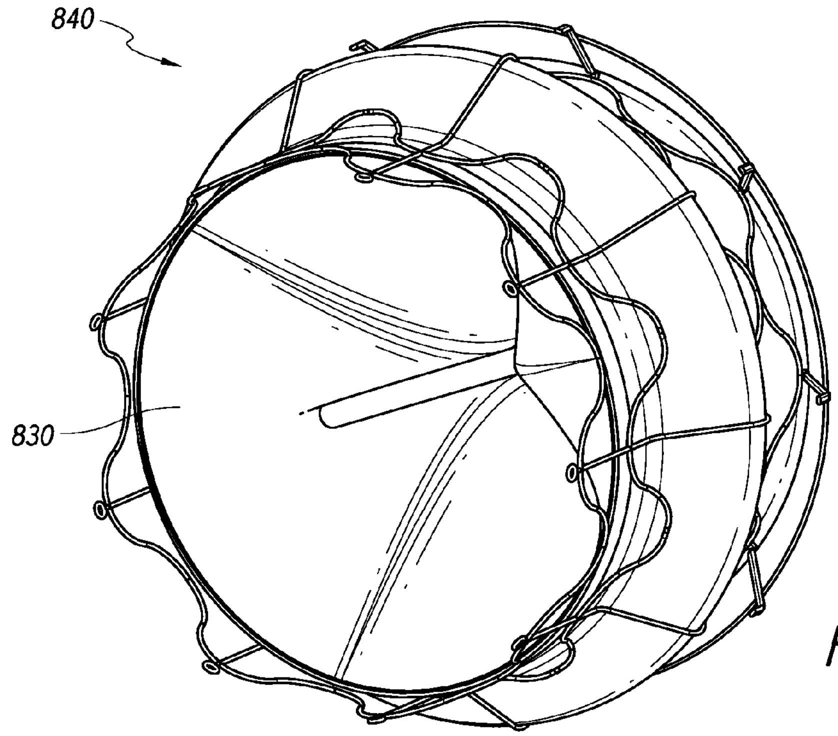


FIG. 25C

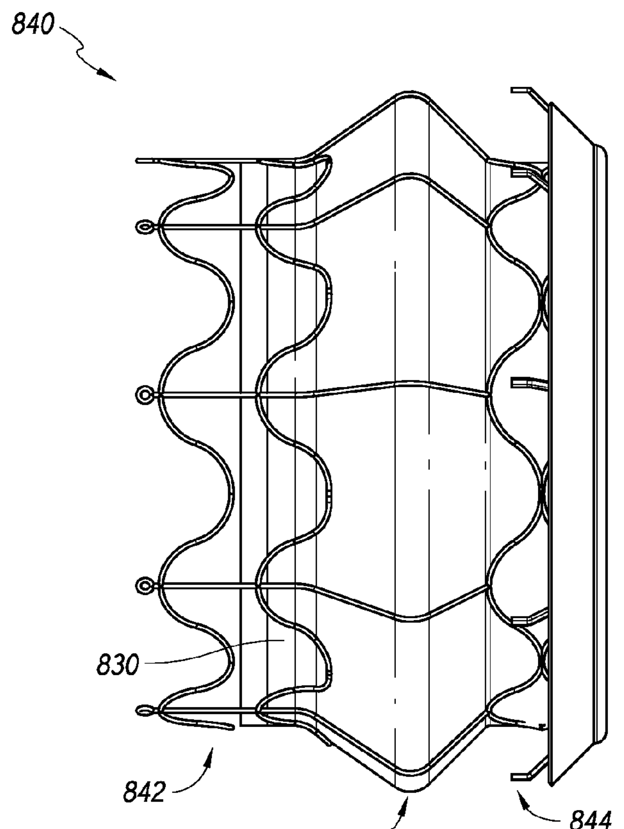


FIG. 25D

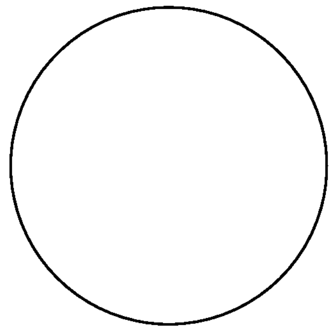


FIG. 26A

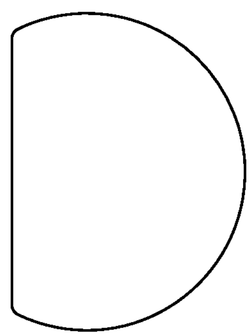


FIG. 26B

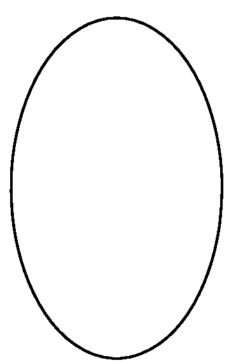


FIG. 26C

VASCULAR IMPLANT AND DELIVERY SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/761,349, filed Apr. 15, 2010, now U.S. Pat. No. 8,414, 644, which claims priority to U.S. Provisional Application Ser. No. 61/169,367, which was filed on Apr. 15, 2009. All of the above applications are hereby incorporated herein by reference in their entirety and are to be considered a part of this specification.

BACKGROUND

1. Field of the Invention

The present invention relates to replacement heart valves and systems for delivering replacement heart valves.

2. Description of the Related Art

Human heart valves, which include the aortic, pulmonary, mitral and tricuspid valves, function essentially as one-way valves operating in synchronization with the pumping heart. The valves allow blood to flow in a downstream direction, but block blood from flowing in an upstream direction. Diseased heart valves exhibit impairments such as narrowing of the valve or regurgitation. Such impairments reduce the heart's blood-pumping efficiency and can be a debilitating and life threatening condition. For example, valve insufficiency can lead to conditions such as heart hypertrophy and dilation of the ventricle. Thus, extensive efforts have been made to develop methods and apparatus to repair or replace impaired heart valves.

Prostheses exist to correct problems associated with impaired heart valves. For example, mechanical and tissue-based heart valve prostheses can be used to replace impaired native heart valves. More recently, substantial effort has been dedicated to developing replacement heart valves, particularly tissue-based replacement heart valves that can be delivered with less trauma to the patient than through open heart surgery. Replacement valves are being designed to be delivered through minimally invasive procedures and even percutaneous procedures. Such replacement valves often include a tissue-based valve body that is connected to an expandable stent that is then delivered to the native valve's annulus.

Development of replacement heart valves and associated delivery systems in which the heart valve is compacted for delivery and then controllably expanded for controlled placement has proven to be particularly challenging. Delivery systems that facilitate accurate positioning and reliable placement have also proven to be challenging to develop, particularly systems that enable repositioning of the valve after partial deployment if it is determined that the valve is not positioned correctly.

SUMMARY

Accordingly, there is in the need of the art for an improved replacement heart valve and an improved system for delivering such heart valves in a reliable and controlled manner. The present invention relates to an implantable heart valve design along with a system and method for delivering and implanting the same.

As discussed in U.S. Provisional Application No. 61/169, 367, in accordance with some embodiments, a prosthetic heart valve can be attached, without sutures, to a pulmonary valve annulus, an aortic valve annulus (including cases where

the native leaflets have been removed), or to an atrio-ventricular valve where the leaflets and subvalvular apparatus can remain intact. Specific attention is paid here to its relevance in the mitral valve position; however, the same technology could be applied to any of the four heart valves depending on the configuration of the design that is used. The implant itself can be comprised of a foldable valve with a plurality of leaflets (utilizing either bovine, equine, or porcine pericardial tissue or a synthetic material), a stent frame, and fabric or tissue-based liner. The valve can be delivered through an open-heart procedure, a minimally-invasive surgical procedure, or remotely through a catheter-based, percutaneous approach.

As further discussed in U.S. Provisional Application No. 61/169,367, in accordance with some embodiments, these and other objects can be achieved by combining a stent frame with a multi-leaflet valve design and a tissue- or fabric-based liner. Some embodiments of the stent frame are made from self-expanding nitinol material; however it could also be made from a self-expanding polymer or a balloon expandable metallic material. In the expanded state, the upper portion of the stent frame may be of a larger diameter than the lower portion. The lower portion sits inside of the native valve annulus (intra-annularly), while the upper portion sits above the native valve annulus (supra-annularly).

In some embodiments, the upper and lower portions of the stent have circular cross-sections; however, it is possible that the upper portion, the lower portion, or the entire stent frame could be formed to have a noncircular cross-section that better approximates the typical cross-section of the native valve annulus in which the prosthetic valve is being implanted. The shoulder that is formed by the transition between the different diameters of the upper and lower portions of the stent frame provides fixation on one side of the native valve annulus and prevents the implant from passing through the native annulus in the axial direction going from the upper portion to the lower portion. The upper portion of the stent frame houses the valve and is designed with a plurality of continuous vertical struts which eliminate foreshortening in that region of the stent frame. As a result, the tensile forces being exerted on the valve material are minimized as it goes from the expanded state to the compressed state during the loading process and from the compressed state to the expanded state during deployment process. The lower portion of the stent frame utilizes the same annular connection mechanism (foreshortening oval cells with anchor features) that is described in U.S. Provisional Application No. 60/735,221. Said features of the stent frame are incorporated by reference to the extent that they are described in U.S. Provisional Application No. 61/169,367 and U.S. patent application Ser. No. 12/084,586, published as U.S. Publication No. 2009/0216314, which claims priority to U.S. Provisional Application No. 60/735, 221.

According to certain embodiments, multiple anchor features can extend from the bottom of each of the oval cells that makes up the lower portion of the stent frame. These anchor features can be formed in such a way so that they extend radially outward from the central axis of the stent frame and can be formed in a number of different configurations to achieve optimal fixation. Likewise, the distal tips of these anchor features can have various configurations to achieve optimal tissue engagement, ranging from an atraumatic tip that will not penetrate the tissue at all to a sharp tip that will embed itself into the tissue to some degree. The anchor features oppose the transition shoulder between the upper and lower portions of the stent frame and provide fixation on the opposite side of the native valve annulus, preventing the implant from passing through the native annulus in the axial direction going from the lower portion to the upper portion. The foreshortening that results from the radial expansion of the oval cells in the lower portion of the stent frame will generate an axial clamping force on the native valve annulus between the transition shoulder and the tips of the anchor features. The stent frame may also include some form of radio-opaque markers (e.g. marker bands on the anchor features) to provide for improved visibility under fluoroscope imaging. It is also possible that the transition shoulder between the upper and lower sections of the frame may include small anchor features that facilitate some engagement with the tissue on that side of the annulus.

As further discussed in U.S. Provisional Application No. 61/169,367, in accordance with some embodiments, the valve portion of the prosthetic heart valve implant can utilize the same design as that described in U.S. Provisional Application No. 61/136,716. Said features of the valve portion of U.S. Provisional Application No. 61/136,716 is incorporated by reference to the extent that they are described in U.S. Provisional Application No. 61/169,367 and U.S. patent application Ser. No. 12/569,856, published as U.S. Publication No. 2010/0082094, which claims priority to U.S. Provisional Application No. 60/136,716. In some embodiments, the outer layer of the valve material can be attached to the interior face of the upper portion of the stent frame using suture material or other means. The leaflet portion of the valve material is folded inside of the outer layer of the valve material and attached to the outer layer and/or the stent frame at the commissural posts and along the edges of the leaflets using sutures or other means. The attachment locations may or may not utilize eyelet holes incorporated into the struts of the stent frame. In some embodiments, the location of the fold between the outer layer and the interior leaflet layer does not extend to the end of the stent frame.

During the delivery process, which will be described in detail below, this leaves some portion of the stent frame exposed so that blood can flow freely through the valve and the valve can begin to function prior to final deployment, which in turn, allows more time and control during the delivery process. The lower edge of the outer layer is attached to the upper edge of the tissue- or fabric-based liner, which is attached to the inside face of the lower portion of the stent frame and folds around to the outside face of the anchor features. In some embodiments, the liner is made from a fabric material to facilitate tissue in-growth at the annular region and, thereby, provide better leak prevention overtime. In addition, a fabric-based liner may allow for a greater degree of elasticity to accommodate the radial expansion and axial contraction in the lower portion of the stent frame caused by the foreshortening process. However, the liner could also be made from a separate piece of tissue material or could be constructed by lengthening the outer layer of the valve material and extending it through the intra-annular region of the stent frame, folding it around the base of the lower portion of the stent frame to the outside face of the anchor features, and attaching the terminal edge in the central region of the anchor features, again using sutures or other means.

In some embodiments, a replacement mitral valve can be configured to be delivered to a native mitral valve and secured relative to a native mitral valve annulus. The replacement mitral valve can include an expandable frame having a proximal end and a distal end and having a longitudinal axis extending between the proximal end and the distal end, the expandable frame being configured to radially expand and contract for deployment within the native mitral valve. In some embodiments, the replacement mitral valve can include a first anchoring portion which can be configured to at least partially engage an atrial side of the native mitral valve annulus, the first anchoring portion including a plurality of circumferentially-spaced anchoring tips connected by at least one row of circumferentially expansible elements. In some embodiments, when the expandable frame is in an expanded configuration, the first anchoring portion can extend radially outwardly from a portion of the expandable frame that has a first cross-sectional dimension such that the at least one row of circumferentially expansible elements can have a second cross-sectional dimension greater than the first cross-sectional dimension. In some embodiments, the replacement mitral valve can include a second anchoring portion distal to the first anchoring portion and having a plurality of anchors extending from the expandable frame which can be configured for placement on a ventricular side of the native mitral valve annulus, wherein when the expandable frame is in an expanded configuration, the plurality of anchors can extend at least partially proximally toward the first anchoring portion. In some embodiments, a valve body can be connected to the expandable frame. In some embodiments, radial expansion of the expandable frame can cause the first anchoring portion and the second anchoring portion to draw closer together. In some embodiments, when the expandable frame is in an expanded configuration, tips of the plurality of anchors of the second anchoring portion can have a third cross-sectional dimension which is at least about the same as the second cross-sectional dimension.

In accordance with one embodiment, the present invention provides a method of loading a device for delivering a self-expanding vascular implant. The method may include drawing a relaxed, expanded vascular implant through an elongate form having a decreasing diameter to a load tube portion having a compacted diameter, engaging a locking end of the implant with a locking mechanism disposed on a support tube, advancing an outer sheath over the engaged locking end and support tube so as to capture the locking end between the sheath and support tube, and advancing the outer sheath over the compacted implant so as to transfer the implant from within the load tube to within the outer sheath.

In one such embodiment, transferring the implant from within the load tube to within the outer sheath comprises further compacting the implant.

As discussed in U.S. Provisional Application No. 61/169,367, In accordance with some embodiments, accurate and controlled delivery, positioning, and deployment of the implant are achieved by using a delivery device that may consist of a steerable introducer sheath, an outer sheath, a support tube, an inner tube, and a nose cone. The inner tube has an internal diameter sized to fit over a standard guide wire and would be securely attached to the nose cone, such that advancing or retracting the inner tube would also cause the nose cone to move accordingly. The outer diameter of the inner tube is sized to move smoothly within the internal diameter of the support tube. The support tube has an outer diameter sized to move smoothly within the internal diameter of the outer sheath. The distal end of the support tube also has a locking feature that, when covered by the out sheath, maintains a connection to the prosthetic heart valve implant via mating features on the end of the stent frame and prevents the implant from being fully deployed and released until the user chooses to do so.

Some embodiments of a trans-catheter, percutaneous system may utilize a steerable introducer sheath whose inner diameter is sized to accommodate the outer diameter of the outer sheath and which has a separate handle that allows for relative motion between this component and the outer sheath, support tube, and inner tube as a separate system. The steerable introducer sheath would be capable of controlled deflection in one or more planes and would be used as needed to attain proper axial alignment between the delivery catheter and the native annular plane such that the two were perpendicular to one another. In another embodiment, the support tube could be constructed to have the same steerable characteristics, allowing for relative motion of both the inner tube and the outer sheath with respect to the deflectable support tube and eliminating the need for the steerable introducer sheath. In the case of an open-chest or minimally-invasive or surgical procedure, the distal end of the delivery device could be shorter, with a stiff shaft for optimal control. In the case of a trans-catheter or percutaneous procedure, the distal end of the delivery device would be longer with a flexible shaft to more easily navigate the vasculature. In both cases, the hand controls at the proximal are similar, as are the mechanics of delivery and deployment at the distal, which are described in detail below.

In accordance with another embodiment, the present invention provides a vascular implant delivery device. The device comprises an elongate support tube having a distal end, a locking mechanism being disposed at or adjacent the distal end. An elongate sheath is adapted to slide over the support tube. A self-expanding vascular implant has a locking member. The support tube locking mechanism is configured to engage the implant locking member so as to block axial movement of the implant when the locking mechanism and locking member are engaged. The sheath has an inner lumen sized to block the implant locking member from moving radially relative to the support tube locking mechanism sufficient to release from the support tube locking mechanism.

In order for the prosthetic heart valve assembly to be delivered, it must first be loaded into the delivery device. To do this several variations of a loading system have been devised that would be capable of controllably reducing the diameter of the stent frame (and thereby reducing the diameter of the tissue valve and fabric liner). Several embodiments of the loading system are described and can include a funnel with a large diameter side capable of accommodating the implant in its expanded form and a small diameter side that will be just larger than the outside diameter of the outer sheath of the delivery device. A component called the octopus puller is inserted through the small side of the funnel and attached to the end of the stent frame of the prosthetic heart valve assembly. It can then be used to pull the prosthetic heart valve assembly through the funnel and reduce the diameter as it does. With the diameter sufficiently reduced, the prosthetic heart valve assembly can be loaded into the delivery device.

In one such embodiment, the self-expanding vascular implant remains connected to the support tube so long as the sheath extends distally past the support tube locking mechanism, and the device is configured so that when the sheath is moved proximally past the support tube locking mechanism, the implant locking member moves radially out of engagement with the support tube.

In accordance with yet another embodiment, the present invention provides a method of delivering a self-expanding vascular implant. The method may include advancing the implant within a patient's vasculature to a desired delivery location, the implant being advanced while maintained in a compacted configuration within a sheath, a first end of the implant being captured between the sheath and a support tube locking mechanism. The method further includes withdrawing the sheath proximally sufficient to enable a second end of the self-expanding implant to expand radially to a fully expanded size while the first end of the implant remains captured. The second end of the implant is positioned in a desired position and orientation while the first end of the implant remains captured. The method further includes withdrawing the sheath proximally sufficient to release the first end of the implant.

In once such embodiment, if it is determined that the second end of the implant is not positioned as desired, the method additionally comprises moving the sheath distally so as to at least partially recapture the implant within the sheath, repositioning the delivery device, and again withdrawing the sheath proximally sufficient to enable the second end of the implant to expand radially.

Other inventive embodiments and features are disclosed below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a heart valve implant having features in accordance with one embodiment.

FIG. **2**A is a plan view of a stent frame of the implant of FIG. **1** in a radially compacted configuration.

FIG. **2**B shows the stent frame of FIG. **2**A in a radially expanded configuration.

FIG. **3** schematically shows an implant as in FIGS. **1**-**2** deployed in a native mitral annulus of a human heart.

FIG. **4**A is a plan view of a stent frame configured in accordance with another embodiment.

FIG. **4**B shows an isometric view of an embodiment of the expanded stent frame.

FIG. **5**A shows a flat cutting pattern for a stent frame as in FIG. **4**A.

FIG. **5**B shows possible eyelet locations within the stent frame to facilitate assembly of the tissue and/or fabric.

FIG. **5**C shows another embodiment of possible eyelet locations within the stent frame to facilitate assembly of the tissue and/or fabric.

FIG. **6** shows a plan view of a stent frame in accordance with yet another embodiment.

FIG. **7**A is a plan view of a stent frame configured in accordance with still another embodiment.

FIG. **7**B is a plan view of a stent frame configured in accordance with yet a further embodiment.

FIG. **7**C is a plan view of the stent frame of FIG. **7**B in a compressed configuration.

FIG. **8**A is a plan view of a stent frame configured in accordance with yet a further embodiment.

FIG. **8**B is a plan view of a stent frame configured in accordance with yet a further embodiment.

FIG. **8**C is a plan view of the stent frame of FIG. **8**B in a compressed configuration.

FIGS. **9**A-E show exemplary embodiments of anchor portions for use with stent frame embodiments as discussed herein.

FIGS. **10**A-D show exemplary embodiments of anchor tip portions for use with stent frame embodiments as discussed herein.

FIG. **11**A shows an embodiment of a delivery device for delivering a valve implant in accordance with one embodiment.

FIG. **11**B shows a distal portion of the delivery device of FIG. **11**A.

FIGS. **11**C-**11**D show several views of one embodiment of the delivery catheter.

FIGS. **12**A-I show a distal end of a delivery device at several stages during a delivery operation in accordance with a preferred embodiment.

FIGS. 13A-C show the delivery device of FIGS. 12A-I at selected stages of the deployment operation in connection with a human heart.

FIGS. 14A-L show an embodiment of a delivery device and an embodiment of a structure for loading an implant onto the delivery device, shown at several stages during a loading operation.

FIGS. 15A-H show another embodiment of a loading device and associated method shown at several stages during the operation of loading an implant onto a delivery device.

FIGS. 16A and 16B show an embodiment of a multi-piece loading device in an assembled and a disassembled configuration.

FIGS. 17A-F show another embodiment of a delivery device and an embodiment of a structure for loading an implant onto such a delivery device, shown at selected stages during a loading operation.

FIG. 18 shows an embodiment of a prosthetic heart valve assembly.

FIGS. 19A-C show isometric views of the functioning valve after it has been deployed.

FIG. 20A shows a perspective view of the expanded stent frame with fabric-liner and with an alternative bend configuration of the anchor features.

FIG. 20B shows a side view of the expanded stent frame of FIG. 20A.

FIG. 20C shows a front view of the expanded stent frame of FIG. 20A.

FIG. 21 shows a cross-section view of another embodiment as it would be positioned and anchored in the mitral valve annulus.

FIG. 22A shows the strut geometry of a stent frame in the pre-expanded condition after the pattern has been laser cut into a tube.

FIG. 22B shows the stent of FIG. 22A in both a flat pattern and expanded configurations to describe the various regions of the stent frame geometry.

FIG. 23A shows a first perspective view of one embodiment of the prosthetic heart valve assembly with the valve positioned in the upper portion of the stent frame.

FIG. 23B shows a second perspective view of the embodiment of FIG. 23A.

FIG. 23C shows a third perspective view of the embodiment of FIG. 23A.

FIG. 23D shows a side view of the embodiment of FIG. 23A.

FIG. 24A shows a first perspective view of one embodiment of the prosthetic heart valve assembly with the valve positioned entirely in the lower portion of the stent frame.

FIG. 24B shows a second perspective view of the embodiment of FIG. 24A.

FIG. 24C shows a third perspective view of the embodiment of FIG. 24A.

FIG. 24D shows a side view of the embodiment of FIG. 24A.

FIG. 25A shows a first perspective view of one embodiment of the prosthetic heart valve assembly with the valve positioned between the upper and lower portions of the stent frame and a flared diameter in the stent frame at the transition between the upper and lower portions.

FIG. 25B shows a second perspective view of the embodiment of FIG. 25A.

FIG. 25C shows a third perspective view of the embodiment of FIG. 25A.

FIG. 25D shows a side view of the embodiment of FIG. 25A.

FIGS. 26A-C show three possible variations of the cross-sectional shape of the stent frame.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present specification and drawings disclose aspects and features of the invention in the context of embodiments of replacement heart valves and delivery systems for delivering replacement heart valves. For illustrative purposes the embodiments disclosed herein are discussed in connection with replacing the patient's mitral valve. However, it is to be understood that the context of a particular valve or particular features of a valve should not be taken as limiting, and features of any embodiment discussed herein can be employed in connection with prostheses and delivery systems for replacing other vascular valves, and features of any embodiment can be combined with features of other embodiments as desired and when appropriate.

As discussed in U.S. Provisional Application No. 61/169,367, referring to FIG. **18**, there is shown a three dimensional view of one embodiment of the prosthetic heart valve assembly **528** intended to be used in the atrio-ventricular position and includes the stent frame **540**, a pericardial tissue valve **530**, and a fabric-based liner **532**. Reference numeral **502** points to the tissue valve in the upper portion of the stent frame **540**, which is the same valve design that is described in U.S. Provisional Application No. 61/136,716. Said valve design of U.S. Provisional Application No. 61/136,716 is incorporated by reference to the extent that they are described in U.S. Provisional Application No. 61/169,367 and U.S. patent application Ser. No. 12/569,856, published as U.S. Publication No. 2010/0082094, which claims priority to U.S. Provisional Application No. 60/136,716. In the mitral position, the upper portion **542** of the stent frame **540** and the tissue valve **530** are designed to sit in the left atrium of the heart just above the mitral valve annulus. As noted in the figures of U.S. Provisional Application No. 61/169,367, in this embodiment, the origami valve design can attach to the upper section **542** of the frame **540** located within the left atrium.

Reference numeral **504** points to the connection region of the stent frame **540** where the shoulder **546** formed by the transition between the upper and lower portions **542**, **544** of the stent frame **540** captures the low-pressure (atrial) side of the valve annulus and the anchor features **548** extending from the bottom of the lower portion **544** of the stent frame **540** captures the high-pressure (ventricular) side of the annulus. The foreshortening action in the lower portion of the stent frame **540** causes the anchor features **548** to move toward the transition shoulder **546** and generates an axial clamping force that securely attaches the implant onto the valve annulus. The cell geometry in this portion of the stent frame **540** utilizes the same annular connection mechanism (foreshortening oval cells with anchor features) that is described in U.S. Provisional Application No. 60/735,221. Said cell geometry of the stent frame **540** are incorporated by reference to the extent that they are described in U.S. Provisional Application No. 61/169,367 and U.S. patent application Ser. No. 12/084,586, published as U.S. Publication No. 2009/0216314, which claims priority to U.S. Provisional Application No. 60/735,221. Each anchor feature **548** is allowed to move independently and allows the stent frame **540** to accommodate variations in the planar anatomy of the valve annulus.

Reference numeral **506** points to the fabric-liner **532** which lines the intra-annular space on the interior face of the lower portion **544** of the stent frame **540** and wraps around to the outside face of the anchor features **548** where it is securely attached using sutures or other means. As further noted in the figures of U.S. Provisional Application No. 61/169,367, in this embodiment, fabric can line the intra-annular space and wrap around the anchors **548** on the ventricular side to prevent leaks. The fabric-liner **532** facilitates tissue in-growth and provides a tighter seal to the surrounding tissue to reduce the risk of paravalvular leaks.

FIGS. **19**A-C show alternative isometric views of the fully deployed prosthetic valve implant **610** with functioning valve leaflets **612**. FIG. **19**A shows the implant **610** from the in-flow side with the valve in the open position. FIG. **19**B shows the implant **610** from the in-flow side with the valve in the closed position. FIG. **19**C shows the implant **610** from the out-flow side with the valve leaflets partially closed **612** (mid-cycle).

With reference to FIGS. **1** and **2**, another embodiment of a replacement heart valve **28** comprises a valve body **30** attached to a stent frame **40**. In this embodiment, the heart valve body **30** is constructed of a tissue-based media such as bovine, equine and/or porcine pericardium. Vascular tissue, as well as other natural and manmade materials such as those described herein that are thin, flexible and durable, may also be employed for the heart valve body.

With particular reference to FIGS. **2**A and **2**B, the illustrated stent frame **40** embodiment supports the valve body **30** and can be expanded from a compacted state as shown in FIG. **2**A to an expanded state as shown in FIG. **2**B. The illustrated stent **40** preferably is a self-expanding stent constructed of a flexible material, preferably a shape memory material such as nitinol. However, as noted in U.S. Provisional Application No. 61/169,367, while a preferred embodiment of the stent frame is made from self-expanding nitinol material, it could also be made from a self-expanding polymer or a balloon expandable metallic material. As it is self-expanding, the stent **40** is in a fully opened state, as depicted in FIG. **2**B, when relaxed. The illustrated stent **40** preferably is elongate from a first end **42** to a second end **44** and is tubular with a longitudinal axis **46** and a generally circular cross section. As noted in U.S. Provisional Application No. 61/169,367, although the preferred embodiment is a circular cross-section (see FIG. **26**A) in order to keep the implant symmetric and minimize the need for radial adjustment during delivery, it is possible to form all or a portion of the stent body into a non-circular cross-section. It is to be understood that in other embodiments stents can have a non-circular cross section, such as a D-shape (see FIG. **26**B), an oval (see FIG. **26**C) or an otherwise ovoid cross-sectional shape. As noted in U.S. Provisional Application No. 61/169,367, these are just two examples of non-circular cross-sections which may prove to be more advantageous, especially with respect to the atrio-ventricular position, in facilitating optimal engagement with the native valve annulus and minimizing the chance of para-valvular leaks.

The illustrated stent frame **40** has a non-foreshortening portion **50** and a foreshortening portion **60**. The portions are joined at a transition **62** between the first and second ends **42**, **44**. Foreshortening refers to a behavior in which the length of the stent **40** in the foreshortening portion **60** decreases as the radius of the stent increases from the compacted state to the expanded, deployed state. As such, in FIG. **2**A, which shows the stent frame **40** in a compacted state, the foreshortening portion **60** of the stent frame **40** is longer than when the stent is in the expanded state illustrated in FIG. **2**B.

With continued reference to FIG. **2**B, the non-foreshortening portion **50** of the illustrated stent **40** comprises a plurality of rows or rings **64***a-c* of circumferentially expansible elements, or struts **65**, arranged in a zigzag pattern. The struts **65** are configured to expand and contract with a change in radius of the stent **40**. In the illustrated embodiment, the stent has three such rings **64***a-c*. It is to be understood that more or fewer rings can be employed as desired to accomplish the purposes of this stent frame.

In the illustrated embodiment, the respective ends of each circumferential undulating strut **65** join an adjacent strut **65** at an apex **66**, **68** which is, in at least some embodiments, an area of preferential bending. In the illustrated embodiment, the zigzag pattern of the rings **64***a-c* are generally in phase with one another. It is to be understood that, in other embodiments, all or most of the rings can be in phase with one another or out of phase as desired.

With continued reference to FIG. **2**B, longitudinal struts **70** extend transversely across the rings **64***a-c* of the nonforeshortening portion **50** from the first end **42** of the frame **40** to the transition **62**. More particularly, each ring **64** shares a common longitudinal strut **70**. The longitudinal struts **70** extend through apices **66** of adjacent rings **64**, and preferably extend the entire length of the nonforeshortening portion **50**. Preferably, the longitudinal struts **70** comprise a nonexpandable rod or bar. The apices **66** that are connected to the longitudinal struts **70** are referred to as "connected" apices **66**. Apices **68** not connected to longitudinal struts **70** are referred to as "free" apices **68**.

As noted above, the longitudinal struts **70** are not substantially expandable in a longitudinal direction. As such, even though the undulating struts **65** provide flexibility in radial expansion or compaction, as the stent **40** changes radial size between the compacted and expanded states, the longitudinal length of the stent in the nonforeshortening portion **50** remains substantially unchanged. In other embodiments, the longitudinal struts may include expansible elements that may allow the struts to expand somewhat longitudinally. However, such longitudinal expansion would not be directly tied to any change in strut radius.

In the illustrated embodiment, a first ring **64***a* is disposed adjacent the first end **42** of the stent and a second ring **64***b* is disposed adjacent the first ring **64***a*. A set of first eyelets **72** is formed at the connected apices **66** of the second ring **64***b*. A set of second eyelets **74** is also formed at the second ends of each longitudinal strut **70**, which in the illustrated embodiment is also at the transition **62**. In a third ring **64***c*, the free apices **68** each comprise a protuberance **80** extending therefrom, which protuberance can also be referred to as an apical anchor **80**. Preferably the apical anchor **80** terminates at a tip **82**. Preferably the struts **65** in the third ring **64***c* are pre-shaped so as to flare radially outwardly when the stent frame **40** is in an expanded state as shown in FIGS. **1** and **2**.

With continued reference to FIGS. **2**A and **2**B, the foreshortening portion **60** of the illustrated stent frame **40** comprises a ring **84** of generally diamond-shaped cells **86** connected to one another at connectors **88**. A first end of each cell **86** is connected to the nonforeshortening portion **50** at the second eyelets **74**. The shape of the foreshortening cells **86** is such that as the stent frame **40** is radially compacted, the foreshortening portion **60** of the stent becomes longitudinally longer and, correspondingly, when the stent frame **40** is expanded radially, the foreshortening portion **60** shortens.

A second end of each cell **86** in the foreshortening portion **60** defines the second end **44** of the stent **40** and also defines a base of an end anchor **90** that extends generally radially outwardly and toward the first end **42** of the stent. An anchor eyelet **92** is formed in each end anchor **90**, preferably between the base and a tip **94** of each anchor **90**.

A first distance is defined between the tips **82**, **94** of opposing apical and end anchors **80**, **90** when the stent **40** is in the compacted state, and a second distance is defined between the tips **82**, **94** of opposing anchors **80**, **90** when the stent **40** is in the expanded state. As shown, the second distance is substantially less than the first distance. As such, due to longitudinal shortening of the foreshortening portion **60**, the anchors **80**, **90** cooperate to grasp onto tissues so as to hold the stent in place.

In preferred embodiments, the stent **40** may be deployed into a heart valve annulus, and positioned when compacted so that the tips **82**, **94** of the opposing anchors **80**, **90** are disposed on opposite sides of the native annulus. As the stent is expanded, the opposing anchors are drawn closer together so as to grasp opposite sides of the native annulus and securely hold the stent in position. As such, the stent can be held securely in position without requiring a substantial radial force against the native annulus.

Applicant's U.S. patent application Ser. No. 12/084,586, which was published on Aug. 27, 2009 as U.S. Publication No. 2009/0216314, discusses embodiments of foreshortening stents with anchors, and can be referred to for further discussion of certain aspects of the illustrated stent embodiment. The discussion in this application concerning structure and operation of embodiments of a foreshortening stent, particularly a foreshortening stent having anchors, is expressly incorporated by reference herein.

Applicant's U.S. patent application Ser. No. 12/569,856, which was published on Apr. 1, 2010 as U.S. Publication No. 2010/0082094, discusses several additional embodiments of stents and associated valve bodies, and can be referred to for further explanation and discussion of additional features and embodiments thereof. The entirety of this application is also expressly incorporated by reference herein.

With particular reference again to FIG. **1**, in this embodiment the valve body **30** is disposed inside the stent **40**. More specifically, a skirt portion **96** of the valve body **30** is sewn to the first eyelets **72** of the stent. A hemmed upstream end of the valve body **30** engages the first eyelets **72** in the nonforeshortening portion **50** of the stent **40**. Valve leaflets are attached to the skirt portion and are configured to open and close during valve operation.

An elongate tubular portion **102** of flexible, longitudinally expandable fabric is attached to a downstream end **104** of the skirt portion **96** in the illustrated embodiment. More particularly, a first end of the fabric **102** is sewn to the downstream end **104** of the skirt portion about the circumference of the skirt portion by a downstream seam, which also connects to the second eyelets **74** of the stent frame **40**. Preferably, the fabric **102** is also sewn to the foreshortening cells **86** at several points by connector stitches **106**.

In the illustrated embodiment, the fabric **102** curves around the second end of the stent frame **40**, generally following the curvature of the end anchors **90**. A second end of the fabric portion **102** is sewn to the anchor eyelets **92**. Preferably, the flexible fabric **102** is sufficiently expandable to move with the foreshortening portion **60** as the stent **40** moves between the compacted state and the deployed, relaxed expanded state. As such, in the illustrated embodiment, the tissue valve body **30** is confined to the nonforeshortening portion **50** of the stent and the flexible fabric **102** spans the foreshortening portion **60** of the stent. Thus, the tissue valve body **30** is not subject to longitudinal expansion and contraction with the stent **40**.

With reference next to FIG. **3**, a schematic representation of the heart valve **28** as discussed above in connection with FIGS. **1** and **2** is depicted installed in a human heart **110**. The heart is shown in cross-section, and represents typical anatomy, including a left atrium **112** and left ventricle **114**. The left ventricle **114** is defined by a muscular wall **116**. The left atrium **112** and left ventricle **114** communicate with one another through a mitral annulus **120**. Also shown schematically in FIG. **3** is a native anterior mitral leaflet **122** having chordae tendinae **124** that connect a downstream end of the anterior mitral leaflet **122** to the muscle wall **116** of the left ventricle **114**. A left ventricle outflow tract **126** extends toward the top of the left ventricle **114**.

As shown in FIG. **3**, the valve **28** of FIGS. **1** and **2** is disposed so that the mitral annulus **120** is grasped between the end anchors **90** and apical anchors **80** in accordance with a method of aligning and deployment of the stent **40** discussed previously. As such, all or most of the stent **40** extends into the left atrium. The portion of the stent **40** disposed upstream of the annulus **120** can be referred to as being positioned supra-annularly. The portion generally within the annulus **120** is referred to as positioned intra-annularly. The portion downstream of the annulus is referred to as being positioned sub-annularly. In the illustrated embodiment, only a part of the foreshortening portion is positioned intra-annularly or sub-annularly, and the rest of the stent **40** is supra-annular.

In the illustrated embodiment, the anterior mitral leaflet **122** has not been removed prior to deploying the replacement valve **28**. Preferably, the posterior mitral leaflet (not shown) also has not been removed prior to deploying the replacement valve. However, in other embodiments, one or both of these natural valve leaflets may be removed before deploying the replacement valve.

As discussed in U.S. Provisional Application No. 61/169,367, FIGS. **20**A-**20**C show multiple views of a stent frame **640** and fabric liner sub-assembly **632** with an alternative anchor feature **648** configuration. In this embodiment, the anchor features **648** incorporate a bulge feature that, in the case of atrio-ventricular valve replacement, may help direct the native valve leaflets and subvalvular apparatus away from the distal tips of the anchor features **648** prior to attachment. In addition, the larger radius of curvature between the lower portion **644** of the stent frame **640** and the anchor features **648** that is created by the bulge feature may help to distribute forces and reduce stress in that region.

FIG. **21** illustrates a lateral, cross-sectional view of the heart showing the embodiment of the prosthetic heart valve implant **628** positioned between the left atrium **112** and the left ventricle **114** with the mitral valve annulus **120** captured between the transition shoulder **646** on the atrial side and the anchor features **648** on the ventricular side. The anterior leaflet **122** of the mitral valve is also depicted and specific attention is drawn to the left ventricular outflow tract **126** to show that it is not obstructed by the presence of the prosthetic heart valve implant **628**.

As shown in U.S. Provisional Application No. 61/169,367, FIGS. **22**A and **22**B show a stent frame, such as stent frame **640**, in its pre-expanded condition after the strut pattern **650** has been laser cut into a tube **652**. It also highlights the locking loop features **654** on the upper edge of the stent frame which engage with mating features on a support tube of the delivery device and are used to maintain control over the implant during the delivery process and prior to final deployment and release. FIG. **22**B shows a flat pattern **650** of the same strut geometry as if the stent frame in FIG. **22**A were un-rolled. An expanded version of the same stent frame (with a fabric liner) is also shown in FIG. **22**B with the various sections of the stent frame numbered and labeled. Section **670** indicates the upper tissue valve portion or area of the stent frame. Section **672** shows an optional group of struts for this embodiment intended to provide additional support the transition shoulder, such as shoulder **646**, or flare region or section depending on the configuration. Section **674** points out the flare radius and flat lip section. In other embodiments this would also refer to the transition shoulder. In both cases, this region of the stent frame is meant to engage the top side of the valve annulus. Section **676** is the lower connection portion or section of the stent frame which provides foreshortening and axial clamping as the stent frame expands radially. Section **678** refers to the anchor features, such as anchor features **648**, which can be bent and formed to a variety of configurations after the flat pattern **650** is cut. As shown in the illustrated embodiment, the anchors are bent back with bulge and tip.

With reference next to FIGS. **4**A and **4**B, another embodiment of a stent frame **140** is illustrated. The stent frame **140** is elongate and has opposing first and second ends **142**, **144**. A first circumferential ring **164***a* comprising undulating struts is arranged adjacent the first end **142**. A second circumferential ring **164***b* of undulating struts is disposed adjacent the first circumferential ring **164***a*. A circumferential foreshortening ring **184** comprised of interconnected generally diamond-shaped foreshortening cells **186** is disposed generally adjacent the second end **144**. A plurality of longitudinal struts **170** extend from the first end **142** toward the second end and terminate at a connection to corresponding foreshortening cells **186**. Preferably, the longitudinal struts **170** pass through the undulating rings **164** and connect to apices of the rings **164**. Preferably a locking member is formed on each longitudinal strut **170** at the first end **142**. In the illustrated embodiment the locking members comprise eyelets **72**.

Anchors **190** extend from the foreshortening cells **186** at the second end **144** of the stent. In the illustrated embodiment, the anchors are bent so as to be directed generally toward the first end **142** and generally radially outwardly.

The elongate portion of the stent **140** through which the longitudinal struts extend is a nonforeshortening portion **150**. The elongate portion of the stent made up of the foreshortening cells comprises a foreshortening portion of the stent. An elongate portion of the stent between the undulating rings **164** and the foreshortening ring **184** is referred to as a transition portion **194**.

In a manner as discussed above in connection with other embodiments, when the stent **140** is radially compacted, the length of the longitudinal section will remain substantially constant, but the length of the foreshortening portion will increase. Correspondingly, when radially expanded from a compacted state to the expanded state as shown in FIG. **4**A, the length of the foreshortening portion will decrease, while the length of the nonforeshortening portion remains the same.

The stent frame **140** is configured to support a flexible valve body having valve leaflets so as to provide a prosthetic heart valve implant. Preferably the valve body is disposed on the inside of the stent frame. This specification presents multiple stent frame embodiments, which can support valve bodies of multiple shapes and configurations so as to provide valve implants. For ease of illustration, this specification and associated drawings will refer to a stent or implant without necessarily discussing or showing the valve body. However, it is to be understood that valve implants are to include a valve body having leaflets.

In the illustrated embodiment, each of the longitudinal struts bends radially inwardly in the transition portion **194** between the second ring **164***b* and the foreshortening ring **184** so as to define a shoulder **192** along which the outer diameter of the stent lessens. As such, and as shown in FIG. **4**A, the diameter of the stent at the first end **142** is greater than the diameter of the stent **140** at the second end **144** when the stent is in the relaxed position. In the illustrated embodiment, the anchors **190** extend radially outwardly sufficient so that tips of the anchors are disposed diametrically about the same as or outwardly from the shoulder. As discussed in U.S. Provisional Application No. 61/169,367, the use of the anchor features on the ventricular side of the stent frame is intended to maximize the stent frame's ability to counteract the high pressures that the atrio-ventricular valves will experience during the systolic portion of the heart's pumping cycle. The bend configuration of the anchor features in this embodiment is different from that shown previously in FIG. **19** in that it does not incorporate the bulge feature and instead has a smaller radius of curvature in the region where the anchor features extend radially outward from the stent frame. A tighter radius in that region is expected to provide further anchoring strength in the axial direction. In addition, this embodiment does not incorporate the additional support struts shown in Section **672** of FIG. **22**B.

As discussed in U.S. Provisional Application No. 61/169,367, FIGS. **23**A-D show a stent frame **740**, similar to stent frame **140** of FIG. **4**A, with a larger diameter upper portion **742** and a smaller diameter lower portion **744** with the valve **730** located solely in the upper portion **742** of the stent frame **740**. Of the three embodiments described herein in connection with FIGS. **23**A-D, **24**A-D and **25**A-D, this embodiment provides the largest possible effective orifice area for the valve **730**. It also minimizes or eliminates foreshortening in the valve region which may provide additional durability in the case of tissue valve materials by reducing any tensile forces that could be acting on the tissue as the stent frame **740** changes diameter during loading and expansion. As shown in the figures of U.S. Provisional Application No. 61/169,367, in some embodiments, the upper portion **742** can have a diameter of 38 millimeters, the lower portion **744** can have a diameter of 32 millimeters and the valve **730** can have a length of 14 millimeters and be tied to the 38 millimeter section sitting in the left atrium.

A variation of this embodiment is shown in FIG. **18** where the stent frame formation **540** and valve **530** location are identical; however in FIG. **18**, the height of the valve **530** has been reduced. This allows blood to flow through the stent frame **540** and around the delivery device, which provides intermediate valve functionality when the implant **528** is partially deployed.

As further discussed in U.S. Provisional Application No. 61/169,367, FIGS. **24**A-D show a same stent frame **740** formation as previously described in connection with FIGS. **23**A-D but with an intra-annular valve **730***b* position. In this configuration, the valve **730***b* is attached to the lower portion **744** of the stent frame **740** resulting in an intra-annular position. As shown in the figures of U.S. Provisional Application No. 61/169,367, in some embodiments, the upper portion **742** can have a diameter of 38 millimeters, the lower portion **744** can have a diameter of 32 millimeters, and the valve **730***b* can have a length of 8 millimeters and tied to the 32 millimeter section. This design minimizes the potential for stagnant blood flow and eliminates any low-flow regions within the left atrium, while still maintaining a single diameter valve.

In a preferred embodiment, the stent frame is initially provided as a circular cross-section nitinol tube. The tube is laser cut according to a pattern corresponding to the struts, cells and the like. The cut tube preferably is electrochemically polished to as to remove rough edges. The cut and polished nitinol tube may be shaped in accordance with a desired manner, such as shaping the anchors to extend radially outwardly, and the nitinol stent frame may be heated-treated to both establish the shape memory and to obtain desired elasticity attributes.

With specific reference to FIG. **5**A, a flat pattern for laser cutting a nitinol tube to form the stent **140** of FIG. **4**A is shown. As indicated, the rings **164** are formed near a first end of the flat pattern and the anchors **190** formed are at an opposite second end of the flat pattern. The rings **164** include the cuts for the undulating struts, and the foreshortening ring **184** includes the cells **186** in a flat configuration. The transition area **194** is shown between the undulating rings **164** and the foreshortening ring **184**. Although the stent is initially cut to the pattern shown in FIG. **5**A, further shaping and manipulation is performed to form it into the shape shown in FIG. **4**A. For example, the stent as a whole is stretched radially, the anchors **190** are bent backwardly, and the longitudinal struts **170** in the transition portion are deformed to form the shoulders **192**. The stent is then heat treated, as appropriate, so as to take on the illustrated desired shape as its relaxed shape.

As further discussed in U.S. Provisional Application No. 61/169,367, FIGS. **5**B and **5**C show the flat pattern stent frame geometry with locations for eyelet holes, **73***a-d*, **75***a-d*, that will be utilized during the assembly process to attach the valve material and the liner material to the stent frame. FIG. **5**B designates potential eyelet locations **73***a-d* in both the tissue area **77** and the fabric liner area **79** of the stent frame **140**. FIG. **5**C shows another variation where the eyelet holes **75***a-d* have been incorporated into the flat pattern stent frame geometry.

In the embodiment illustrated in FIG. **4**A, there is no outwardly-extending anchor barb upstream from the anchors **190**. Preferably, in practice, the stent **140** is placed so that the valve annulus is captured between the anchors **190** and the shoulder **192**. As such, the shoulder **192** and anchors **190** cooperate to hold the stent **140** in place, preventing the stent from being forced either way through the native annulus.

With reference next to FIG. **6**, another embodiment of a stent **140***a* is shown, having structure similar to the stent **140**. However, in the transition portion **194** of stent **140***a*, the longitudinal struts **170** bend along their length to extend radially outwardly, and then bend again to extend radially inwardly so as to define an outward flare **196**. In the illustrated embodiment, at least portions of the undulating struts **65** of the second undulating ring **164***b* take on the curvature of the at least part of the flare **196**.

In a manner similar to the embodiment of FIG. **4**A, the flare portion **196** of the transition portion **194** effectually creates a shoulder **192**. However, in the stent **140***a* embodiment illustrated in FIG. **6**, the diameter at the first end **142** of the stent **140***a* is substantially the same as the diameter of the stent at the second end **144**. Preferably, and in a manner having similarities to the discussion above, during valve deployment, the native valve annulus will be captured in the area between the anchors **190** and the shoulder **192**. In a preferred embodiment, the flat cut pattern as illustrated in FIG. **5**A can be formed into the shape of stent **140***a*. Thus, multiple stent shapes can be formed from the same cut pattern.

As discussed in U.S. Provisional Application No. 61/169,367, FIGS. **25**A-D show a stent frame **840**, similar to stent **140***a* of FIG. **6**, with a smaller diameter upper portion **842**, a central flare **843** to provide the transition shoulder, and a smaller diameter lower portion **844** (equal to that of the upper portion **842**). Here the upper edge of the valve **830** is attached in the center of the upper portion **842** of the stent frame **840**, while the lower edge of the valve **830** and the commissural posts **834** of the interior leaflets are attached in the lower portion **844** of the stent frame **840**. This configuration maintains a consistent diameter for the valve **830** while allowing for longer leaflets which could offer improved hemodynamics by minimizing opening and closing angles of the valve leaflets. As shown in the figures of U.S. Provisional Application No. 61/169,367, in some embodiments, the upper portion **842** can have a diameter of 32 millimeters, the outward flare **843** can have a diameter of 38 millimeters, the lower portion **844** can have a diameter of 32 millimeters, and the valve **830** can have a length of 16 millimeters and be tied to the upper and lower 32 mm sections.

There are two options shown for possible anchor features that may be added to the upper section of the stent frame to offer additional fixation. In the atrio-ventricular position, this would correspond to additional fixation on the atrial side of the annulus. With reference to FIG. **7**A, yet another embodiment of a stent **140***b* has a structure much like that of stent **140**. However, as shown, an upstream anchor **190***b* extends from each of the free apices **118** of the second ring **164**. Preferably the upstream anchors **190***b* extend distally past the initial bend of the shoulder **192**. As discussed in U.S. Provisional Application No. 61/169,367, in an embodiment, the anchor **190***b* would extend downward from the supporting struts in the upper section of the stent frame and would be equally spaced between the contact points of the opposing anchor features extending from the lower portion of the stent frame. As noted in U.S. Provisional Application No. 61/169,367, in an embodiment the contact location would be the same radial distance from the edge of the annulus. In this embodiment, during valve deployment, a native annulus preferably is captured between and engaged by the anchors **190**, shoulders **192** and upstream anchors **190***b*. An embodiment of another stent **140***d*, similar to stent **140***b*, is illustrated in FIG. **7**B in an expanded state and FIG. **7**C in a collapsed state.

With reference next to FIG. **8**A, still another embodiment of a stent **140***c* having basic structure very similar to stent **140** of FIG. **4**A is illustrated. In the illustrated embodiment, the longitudinal struts **170** bend in a transition portion **194** so as to define a shoulder **192**. However, as shown in the illustrated embodiment, at or near the beginning of the inward radial bend, the longitudinal struts each split into three arms **198***a*, **198***b*, **190***c*. First and second arms **198***a, b* cooperate to define a cell which preferably extends the length of the shoulder **192** from the point of bending to a foreshortening cell **186** of the foreshortening ring **184**. A third arm **190***c* between the first and second arms **198***a, b* extends from the bend portion toward the second end **144** of the stent **140***c* and radially outwardly so as to define a strut anchor **190***c* generally opposing the corresponding downstream anchor **190**. As discussed in U.S. Provisional Application No. 61/169,367, in an embodiment, the anchor **190***c* would extend outward at the start of the transition shoulder **192** and would be aligned with the tips of the opposing anchor features extending from the lower portion of the stent frame. As noted in U.S. Provisional Application No. 61/169,367, in an embodiment the contact location would be the same radial distance from the edge of the annulus. In a manner similar to other embodiments discussed above, during valve placement, preferably a native valve annulus is captured in the space between the downstream anchor **190** and the strut anchor **190***c*. The stent **140***c* is held securely in place by the opposing anchors **190**, **190***c*, and shoulder **192**. An embodiment of another stent **140***e*, similar to stent **140***c*, is illustrated in FIG. **8**B in an expanded state and FIG. **8**C in a collapsed state.

In the embodiments discussed above, stent frames have been described in which upstream end of the stent has a diameter greater than a downstream end of the stent, and embodiments have been described in which the upstream and downstream ends have substantially the same diameter. It is also to be understood that other stent embodiments may have a downstream end having a greater diameter than an associated upstream end.

In the stent frame embodiments discussed above, the stents are cut from a tube having similarities to the embodiment shown in FIG. **5**A, and the anchors are formed during processing by bending the anchor portions backwardly and radially outwardly. It should be understood that a plurality of anchor shapes may be employed as desired. For example, with reference next to FIG. **9**A, one embodiment of an anchor **90***a* comprises a relatively large base radius having a generally "U"-shaped bend. FIG. **9**B shows an anchor **90***b* also having a relatively large base radius but then continuing bending about the radius beyond 180° so as to define a bulged feature before bending again so as to extend toward the first end of the stent. FIG. **9**C presents an anchor **90***c* having a relatively tight base radius leading to an outward bend and then another bend back inwardly so that the anchor tip is directed generally parallel to or slightly outwardly from a longitudinal axis of the stent. FIG. **9**D illustrates an anchor **90***d* with a relatively large base radius leading to an outward bend before bending back inwardly so that the anchor tip is directed generally parallel to or slightly outwardly from a longitudinal axis of the stent. FIG. **9**E shows an anchor **90***e* having a tight base radius that completes only about a 130°-160° turn, and then continues to curve slightly along its length having a very long bending radius so as to approach, but not necessarily complete, a 180° turn at its tip.

In the illustrated embodiment, the tips of the anchors have been shown as generally pointed or flat. It is to be understood that numerous tip configurations can be employed as desired to optimize the engagement and attachment of the replacement heart valve to the native valve annulus. For example, FIG. **10***a* shows an anchor tip **92***a* having a smooth radius configured to limit trauma to the tissue. FIG. **10***b* illustrates an embodiment of an anchor tip **92***b* having an expanded ball radius. Such a ball radius can be created as a two-dimensional circular shape during the laser cutting process, or can be a three-dimensional sphere attached to the anchor tip during, for example, a ball welding procedure. FIG. **10***c* shows a pointed anchor tip **92***c* configured to provide some degree of penetration into the tissue of the valve annulus. FIG. **10***d* illustrates a flared anchor tip **90***d* configured to distribute anchor forces over a surface area of tissue, but also comprising a serrated edge to penetratingly engage such tissue. In additional embodiments a flared tip may have a smooth edge. Additionally, further tip configurations can be employed as desired to optimize engagement and fixation for different valves and different disease morphologies. In further embodiments, as noted in Provisional Application No. 61/169,367 different tip configurations can be combined within a single stent frame to further optimize engagement and fixation as needed.

The embodiments as disclosed above in connection with replacement heart valves can be delivered to a patient's heart valve annulus in various ways, such as by open surgery, minimally-invasive surgery, and percutaneous, or transcatheter, delivery through the patient's vasculature. With reference next to FIGS. **11**A and **11**B, an embodiment of a delivery device **200** is shown in connection with a replacement heart valve. The illustrated embodiment comprises an elongate, steerable delivery catheter configured to be advanced through a patient's vasculature in a percutaneous delivery approach. The illustrated device **200** comprises an elongate inner tube **202** that is attached at its distal end to a nose cone **204**. The inner tube **202** has a lumen sized and configured to slidably accommodate a guidewire **206** so that the device **200** can be advanced over the guidewire **206** through the vasculature. A support tube **208** concentrically encircles the inner tube **202** and is sized to be slidable over the inner tube. An outer sheath **210** is disposed so as to be slidable over the support tube **208**. In the illustrated embodiment, and preferably, in a manner as discussed in embodiments presented below, the support tube **208** and outer sheath **210** cooperate to grasp onto an end of the replacement heart valve, which, for ease of illustration, is here represented by showing only a stent frame. For delivery, the valve is compacted and held within the outer sheath **210**. As noted in Provisional Application No. 61/169,367, the device shown here represents a percutaneous or trans-catheter embodiment of the delivery device. In a surgical or minimally-invasive embodiment, the components would remain the same, however, the overall length of the system would be shorter and flexibility of the sheath and tube components may or may not be required.

With reference next to FIGS. **12** and **13**, delivery device **220** configured in accordance of one embodiment is shown at various steps along a sequence or method of valve implant deployment. More specifically, FIGS. **12**A-**12**I demonstrate schematic views of various steps of a deployment process, and FIGS. **13**A-**13**C show the state of the delivery device **220** relative to a native heart valve annulus **120** at certain stages of deployment. In the embodiment illustrated in FIG. **13**, the deployment device **220** deploys the heart valve implant **222** into a patient's native mitral annulus **120**. It is to be understood, however, that features and aspects as discussed herein may be employed when employing valves elsewhere in a patient's heart or other vasculature.

With specific reference to FIG. **13**A, in use preferably the delivery device **220** is advanced into the patient's heart **110** so that a distal end including a nose cone **224** passes through the diseased native valve and through the native annulus **120**. As such, the delivery device **220** preferably is positioned so that the anchor portions **226** of the valve implant **222**, though still compacted within an outer sheath **230**, are disposed generally on a side of the native annulus opposite an approach direction. Once the delivery device **220** is in place, and as next depicted in FIG. **12**A, the outer sheath **230** begins to be retracted thereby exposing the distal, or anchor end **232**, of the valve implant **222**. In the illustrated embodiment, barb-shaped anchors **226** are disposed at the anchor end **232**. It is to be understood that other embodiments may employ other anchor structures. As the outer sheath **230** continues to be retracted as shown in FIG. **12**B, more of the stent **222** is exposed and the anchor end of the stent begins to expand radially as progressively shown in FIGS. **12**B, C and D. However, and as more particularly shown in FIG. **12**D, a proximal end **234** of the stent frame **222** is still held securely within the outer sheath **230**, preferably by the outer sheath cooperating with a support tube so as to restrain the proximal end **234** of the stent **222** from being released from the delivery device **220**. Nevertheless, since the distal portion **232** of the stent has been substantially released it is free to expand and, in the embodiment shown in FIG. **12**D, the distal end **232** of the stent can expand to its fully expanded state while the proximal end of the stent remains restrained within the outer sheath.

With additional reference now to FIG. **13**B, when the distal end **232** is fully expanded a slight back pressure preferably is applied to the entire delivery device **220** so as to pull the stent **222** proximally and seat the implant **222** and particularly the anchor features **226**, against the native annulus. In the illustrated embodiment, the anchor features **226** are seated against the subvalvular side of the initial annulus **120**. Proper seating of the implant can be confirmed via tactile feedback, external imaging, and/or other suitable methods.

With continued reference to FIGS. **12** and **13**, if, for example, data indicates that the placement of the stent frame **222** should be modified, such as due to improper seating, alignment, engagement or the like. The implant **222** can be at least partially resheathed and repositioned. For example, with particular reference to FIGS. **12**E and **12**F, since the implant has not been fully deployed from the outer sheath **230**, the outer sheath **230** can be moved distally, thus engaging and compacting the stent frame so as to force it back into the outer sheath. Such compaction will remove the implant **222** from its faulty positioning. The implant can then be repositioned and redeployed in a new position by again moving the outer sheath **230** proximally as depicted in FIG. **12**G.

Once it is determined that the implant **222** is correctly seated, with the anchors **226** disposed as desired in the subvalvular side of a native annulus, the implant can be completely released from the delivery device **220**. Preferably, and with reference next to FIG. **12**H, such complete release comes when the outer sheath **230** continues to be retracted proximally, exposing the proximal end **230** of the stent frame **222** and disengaging the locking mechanism between the stent frame, support tube and outer sheath. As such, the entire stent becomes free of any constraint by the delivery device and expands freely as depicted in FIGS. **12**I and **13**C so that the implant is fully deployed at the native annulus.

As shown in FIG. **13**C, preferably a foreshortening portion of the stent **222** is generally aligned with the native annulus **120** so that the annulus is captured between the anchor features **226** and an opposing anchor feature such as a shoulder portion of the stent. Of course, in other embodiments, other configurations of anchoring portions may or may not include a shoulder, may include upstream and downstream anchors, and/or may include other structure for engaging one or both sides of an annulus. Once the implant is fully deployed, preferably the sheath is again moved distally to re-engage the nose cone, and the delivery device is removed from the patient.

In the embodiment discussed and illustrated in connection with FIGS. **12** and **13**, only a distal portion of the delivery device **220** is shown. It is to be understood that such a distal portion may be employed in multiple delivery device configurations. For example, a percutaneous, transcatheter-approach delivery device such as shown in FIGS. **11**A and **11**B can employ a distal portion similar to that in the embodiment shown in FIGS. **12** and **13**. Also, delivery devices for us in minimally-invasive or even open surgical procedures may have similar structure and similar operation principles although such devices may advantageously have some different mechanical properties such as increased stiffness, than do embodiments used in trans-catheter approaches.

With reference next to FIGS. **14**A-**14**L, an embodiment of a delivery device **238** and a method and apparatus for loading a heart valve implant **128** onto the delivery device is shown. With reference first to FIG. **14**A, the loading apparatus comprises a compacting device **240** which, in the illustrated embodiment, is generally funnel-shaped. The funnel **240** is elongate and comprises a first and second end **242**, **244**. The first end **242** has a comparatively large diameter and the second end **244** has a comparatively small diameter. A transition **246** progressively decreases the diameter between the first and second ends. Preferably, an elongate compaction portion **250** is disposed at and adjacent second end **244**. Preferably, the diameter within the compacted portion **250** is generally constant along its length and approaches or matches the diameter of the second end **244**.

A cap **252** is provided and is shaped to fit through the first or large end **242** of the funnel **240**. Preferably an outer surface of the cap **252** is configured to fit generally complementarily against the inner surface of the funnel **240**. A first end **254** of the cap **252** is configured to fit generally onto and hook onto the first end **242** of the funnel. A second end **256** of the cap **252** is configured to fit within the funnel and preferably proximal of the compacting portion **250** of the funnel **240**. The second end of the cap preferably comprises a blocking structure.

With continued reference to FIG. **14**A, an example heart valve **128** is shown. In the illustrated embodiment, the heart valve comprises the stent frame **140** described above in connection with FIG. **4**A. To aid in simplicity of illustration, only the stent frame, and not the valve body, is shown. It is to be understood, however, that in practice preferably a completely assembled heart valve implant is employed. Additionally, it is to be understood that implants and stents having configurations other than the specifically shown implant can make use of a compacting apparatus and delivery device having features in accordance with the features and principles discussed in connection with this embodiment. However, this structure and method are particularly preferred in connection with implants having self-expanding stents.

As shown in FIG. **14**A, preferably, the first end **242** of the funnel **240** has a diameter large enough to accommodate the fully expanded, at rest stent frame **140**. Further, preferably, the stent frame is positioned so that its first end **142**, at which the locking members **72** are disposed, is facing toward the funnel. In the illustrated embodiment, the locking members comprise eyelets. Other structures may be employed in other embodiments.

A pull member **260** or "octopus" preferably comprises a pull ring **262** that is connected to a plurality of elongate arms **264**. Each of the arms preferably terminates in a hook **266** or other securing member that is configured to engage one of the locking members/eyelets **72**. Preferably, there are the same number of arms **264** as there are eyelets **72**. Additionally, preferably the arms are substantially flexible so as to appropriately distribute forces and to obtain secure purchase on the stent frame. In one embodiment, the arms **264** comprise a suture material, although various types of string and even semi-rigid plastics, wires or the like may be employed.

With additional reference to FIG. **14**B, an O-ring **270** is preferably disposed about the compacting portion **250** of the funnel **240** and generally adjacent the second end **244** of the funnel. In the illustrated embodiment, the O-ring **270** is an inwardly biased broken ring shape having a pair of tabs **272** adjacent the break in the ring. The tabs assist in placing the ring over the compacting portion **250** of the funnel and other side manipulating the O-ring. Preferably, the O-ring **270** is configured so that its at-rest position is at a diameter substantially less than the diameter of the compaction portion.

With reference next to FIG. **14**C, in operation preferably the octopus arms **264** are threaded through the open second end **244** of the funnel, out the first end **242** of the funnel, and engaged with the implant **128** so that each octopus hook **266** connects to one of the eyelets **72**, on the stent frame **140**. The pull ring **262** is then pulled so as to pull the implant into and through the first end of the funnel. As the pull ring continues to be pulled distally, the stent engages the inner surface of the funnel at the transition **246** and is forced to be radially compacted as the stent **140** is pulled through the funnel **240** until it is substantially compacted within the compaction portion **250** of the funnel and with the locking members **72** of the stent frame extending out of the second end of the funnel as shown in FIG. **14**D.

With continued reference to FIG. **14**D, once the implant has been pulled into the compaction portion **250** of the funnel so that the locking member portions of the frame are exposed and extend out of the second end of the funnel, the cap **252** preferably is inserted through the first end of the funnel so that its second end **256** is generally adjacent the second end **144** of the stent frame. The blocking structure at the second end of the cap **252** preferably is configured to prevent the stent frame from moving backwards out of the funnel. For example, the cap may have a thickness that substantially blocks such backwards movement. Other structures such as partial or full blocking of the funnel may also be employed. With the cap in place, the octopus arms are disengaged from the locking members as shown in FIG. **14**E.

With reference next to FIG. **14**F, additional structure of the delivery device is illustrated in connection with the funnel **240** and implant **128** in the configuration of FIG. **15**E. As shown, the delivery device **238** comprises an elongate inner tube **274** that is connected to a nose cone **276**. Preferably, the inner tube **274** has a lumen sized and adapted to accommodate a standard guidewire **278** extending therethrough. The nose cone **276** preferably has a generally atraumatic tip portion **280** at its distal end and has a cavity **282** formed in its proximal end. A circumferential skirt **284** extends from the proximal end of the nose cone **276** and an inner surface **286** of the circumferential skirt **284** defines the cavity **282**.

An elongate support tube **290** has a lumen sized and configured to slidably accept and slide over the inner tube **274**. A locking mechanism **292** comprising a plurality of locking features **294** is disposed adjacent a distal end of the support tube **290**. In the illustrated embodiment, the locking features comprise bosses **294** extending radially outwardly from an outer surface of the support tube. The illustrated bosses **294** are sized and shaped to generally matingly fit the eyelets of the stent frame **140**.

An outer sheath **300** is configured to fit slidably over the support tube **290**. The outer sheath **300** has a thickness defined between an outer surface **302** and an inner surface **304**. A diameter of a lumen of the outer sheath is defined by the inner surface **304** and preferably the lumen diameter **75** such that the inner surface just clears the locking bosses **294** of the support tube, as will be discussed and shown in more detail below. A raised portion **306** of the outer sheath **300** is disposed near but spaced from a distal end of the outer sheath, and a seat **308** is defined on the distal end of the raised portion **306**. As will be discussed in more detail below, the raised portion and seat **308** are configured to engage a proximal end of the nose cone circumferential skirt **284**.

Although the delivery device has just been introduced in connection with FIG. **14**F, it is to be understood that, in some embodiments, the funnel is threaded over the delivery device so that the funnel concentrically surrounds the inner tube and is disposed between the nose cone and the support tube before the heart valve implant is loaded into the funnel. Thus, in some embodiments, preferably the heart valve is loaded into and compacted within the funnel while the funnel is already disposed over the inner tube of the delivery device.

With reference next to FIG. **14**G, with the implant loaded into the compaction portion of the funnel, the support tube **290** preferably is advanced distally so that the eyelets **72** of the implant **140** are generally aligned with the bosses **294** of the support tube. However, in the illustrated embodiment, the diameter of the compaction portion **250** of the funnel is greater than the diameter of the support tube **290**, and thus the eyelets **72** are disposed radially outwardly from the bosses **294**. With reference next to FIG. **14**H, preferably the inwardly biased O-ring **270** is slipped off of the end of the funnel and onto the exposed connecting portions of the stent frame so as to urge the eyelets inwardly and into engagement with the aligned bosses. The implant is thus connected to the support tube **220**.

With reference next to FIG. **14**I, with the eyelets **72** and bosses **294** engaged, the outer sheath is then advanced distally over the support tube **290** so that the distal end of the outer sheath extends over and distally past the bosses. As discussed above, the lumen diameter of the outer sheath is chosen so that the inner surface **304** just clears the bosses **294** of the support tube. Thus, when the outer sheath is moved distally past the bosses when the bosses are engaged with the eyelets **72**, the eyelets are captured between the outer sheath **300** and support tube **290**, and the first end of the stent is securely held by the support tube. With the eyelets now fully captured, the O-ring is removed.

With reference next to FIG. **14**J, the outer sheath **300** continues to be moved distally relative to the support tube **290** and attached implant **140**. In the illustrated embodiment, the outer sheath inner diameter is less than the diameter of the funnel compaction portion. Thus, as the outer sheath is moved distally, it progressively radially compacts the heart valve implant. As the implant is progressively compacted within the outer sheath, the funnel **240** preferably is also moved distally so that the implant is progressively transferred from being contained within the funnel to being contained within the outer sheath **300**. Eventually, the funnel is completely removed from the implant and the outer sheath contains the implant from its first to its second end, as shown in FIG. **14**K.

In the embodiment illustrated in FIG. **14**K, the stent frame **140** of the implant has anchors **190** extending radially outward at the second end **144**. Those anchors are not captured within the outer sheath in this embodiment, although the outer sheath preferably captures substantially the rest of the stent frame therewithin.

With the implant captured in the outer sheath, the funnel preferably can be removed from the delivery device. In the illustrated embodiment, the smallest diameter portion of the funnel is greater than the outer diameter of the nose cone. Thus, the funnel can be removed by moving it distally over the nose cone. In other embodiments, the funnel may have a lesser diameter than the nose cone, and can be moved by other means such as by cutting the funnel. In still other embodiments, the funnel can have a multiple piece and/or hinged construction and may be held closed by a releasable clamp, clip, or the like. As such, once it has served its purpose and the implant is transferred to the outer sheath, the funnel can be disassembled and/or opened and removed without necessarily drawing the funnel over the nose cone.

With reference next to FIGS. **14**K and **14**L, with the funnel removed and the implant substantially captured within the outer sheath **300**, the nose cone **276** is pulled proximally until as shown in FIG. **14**L, the skirt portion **284** of the nose cone engages and compacts the anchors **190**, and eventually the proximal end of the nose cone skirt engages the seats **308** defined on the raised portion of the outer sheath. The anchors **190** are thus secured between the nose cone skirt inner surface **286** and the outer sheath outer surface **302**. The implant is thus fully contained within the delivery device **238** which preferably maintains a substantially contiguous outer surface. The implant may be delivered to a native heart valve annulus in a manner having similarities to the embodiment discussed above in connection with the FIGS. **12** and **13**.

In the embodiment discussed above in connection with FIG. **14**, the nose cone **276** is depicted as rigidly attached to the inner tube **274**. In another embodiment, the nose cone may be selectively detachable from the inner tube so that the valve implant can be independently drawn into a funnel compaction apparatus, without the funnel being mounted over the delivery device. Thus, a loaded funnel as depicted in FIG. **14**E can be advanced over an inner tube, and then the nose cone may be attached to the inner tube. In such an embodiment, the funnel may have a smaller diameter than as shown and discussed above, as the funnel is not necessarily of large enough diameter to be drawn over the nose cone, and instead the nose cone may be removed in order to remove the funnel. In fact, in such an embodiment and in some options of such an embodiment, the nose cone is not attached to the inner tube until after the funnel is removed and the implant is substantially captured within the outer sheath.

With reference next to FIGS. **15**A-H further embodiments of a device for loading a heart valve implant **128** onto a delivery device **238** are shown. For ease of illustration, the same implant **128**/stent frame **140** used in connection with the embodiment described in FIG. **14** is employed, as well as other similar structures, such as the pull member **260**, and delivery device **238** structure such as the inner tube **274**, nose cone **278**, support tube **290** and outer sheath **300**.

With particular reference to FIG. **15**A, the illustrated embodiment comprises a two-piece compaction device **310** comprising a funnel portion **315** and a loading tube portion **320**. Preferably, the funnel portion **315** and the loading tube portion are detachably connected to one another. Further, preferably the loading tube portion **320** is elongate and has a substantially constant diameter. As with other embodiments, preferably the octopus arms **264** of the pull member **260** extend through the compaction device **310** to hook onto and engage portions of the implant **128**, **140**. In the illustrated embodiment, the hooks **266** engage the stent **140** at the second end **144** of the stent.

In practice, the pull ring **262** is pulled so as to pull the stent into the compaction device and through the funnel portion **315** to radially compact the stent **140**. Preferably, however, a loading inner tube **328** is arranged concentrically within the stent **140** as it is being compacted. As shown in FIG. **15**B, the implant **128**, **140** eventually is radially compacted within the loading tube **320** and concentrically surrounding the loading inner tube **328**. As shown in FIG. **15**B, preferably the loading tube **320** has a length that is somewhat less than the total length of the stent **140** when the stent is in its compacted arrangement. As such, at least the eyelets **72** of the first end **142** extend beyond an end of the loading tube **320**.

With reference next to FIG. **15**C, once the implant **128** is compacted within the loading tube **320**, the pull member **260** may be detached from the implant and the loading tube may be detached from the funnel portion **315** so that the loading tube end associated compacted stent **140** and inner loading tube **328** can be independently moved and manipulated.

FIG. **15**C shows an embodiment in which the delivery device **238** is configured so that the nose cone **276** can be releasably detached from the inner tube **274**. Preferably, the inner loading tube **328** defines an inner lumen having a diameter greater than the outer diameter of the inner tube **274** so that the inner loading tube can be threaded over the inner tube so as to place the compacted implant **128**, **140** on the delivery device **238** between the nose cone **276** and the support tube **290**. In another embodiment, the nose cone is not detachable from the inner tube. Thus, in order to get the compacted implant disposed on the delivery device **238**, the implant is threaded onto the inner tube **274** before the support tube **290** and outer sheath **300** are threaded over the inner tube **274**.

In either case, however, once the support tube **320** with its accompanying compacted implant are threaded over the inner tube **274** as desired, the inner loading tube preferably is removed from within the compacted implant and removed from the delivery device. For example, in the embodiment illustrated in FIG. **15**C, the loading inner tube **328** can be removed distally off the end of the inner tube **274** when the nose cone **276** is detached. In other embodiments, the loading inner tube **328** can be slid off of the inner tube **274** before the support tube **290** and outer sheath **300** are advanced over the inner tube **274**. As such, and as shown in FIG. **15**B, the loading tube **320** with its attendant compacted implant **128**, **140** is disposed on the inner tube **274** between the nose cone **276** and the support tube **290**.

With reference next to FIGS. **15**E-**15**H, preferably the delivery device **238** is then manipulated and operated in a manner similar to that as discussed above in connection with FIGS. **14**G-K so as to capture the first end **142**, and more specifically the eyelets **72**, of the stent frame **140** within the outer sheath **300** using a method of apparatus including the support tube **290** and bosses **294**, although other configurations of locking mechanisms **292** may be employed as desired.

With specific reference next to FIG. **15**G, in one embodiment, after the implant has been captured within the outer sheath **300**, the loading tube portion **320** preferably is removed from around the delivery device **238**. In the embodiment illustrated in FIG. **15**G, the loading tube **320** can be moved proximally over the outer sheath **300** as the outer sheath engages the nose cone **276**. In the embodiment illustrated in FIG. **15**H, the loading tube **320** is advanced distally so as to be removed over the nose cone **276** as the outer sheath also is distally to engage the nose cone **276**.

In the illustrated embodiments, the loading tube **320** has a lumen diameter sufficiently large so that it can be removed over the nose cone **276**, or at least clear the raised portions **306** of the outer sheath **300**. In other embodiments, however, the loading tube may have a lumen diameter more closely approaching the inner diameter of the outer sheath lumen. Removal of the loading tube **320** after the implant is sheathed within the outer sheath **300** may involve breaking or cutting the loading tube **320** or, in other embodiments, the loading tube comprises multiple pieces that can be disassembled or opened so as to remove the tube from the delivery device **238**.

In one of the embodiments discussed above, the nose cone is detachable from the inner tube. It should be understood that, in one such embodiment, the nose cone is not reattached to the inner tube until after the compacted stent is at least partially pulled into the outer sheath, and the loading tube is removed from the delivery device **238**. As such, in this embodiment, the loading tube can have a lumen diameter less than an outer diameter of other structures of the delivery device.

In the embodiments discussed above, an inwardly-biased O-ring **270** is employed to urge locking members **72** of the stent into engagement with locking bosses **294** of the support tube **290**. It is to be understood, however, that other methods and structures can be employed to engage the locking members of the stent with the support tube. For example, a user can manually urge the locking members into engagement with the bosses. Additionally, other structures, such as a belt, specially-configured clamping pliers, or the like can be employed to urge the locking members into engagement with one another. It is contemplated that yet further structures can be employed for this purpose.

With reference next to FIGS. **16**A and **16**B, another embodiment of a multi-piece compaction device **410** comprises a funnel portion **415** and an elongate load tube **420** that are detachably connected to one another. The funnel portion and load tube preferably share at least some features with other embodiments discussed in this specification. In the illustrated embodiment, the smaller end of the funnel portion comprises an L-lock track **417** formed therein. The load tube **420** comprises an overlap portion **422** having a lock member

424. A diameter of the overlap portion **422** is reduced so that the overlap portion will fit within the end of the funnel portion **415** at the L-lock track **417**. The lock member **424** is slidable within the track **417** so as to detachably secure the funnel portion **415** and load tube **420** together. It is to be understood that other structures can be employed to detachably connect the funnel and load tube.

With reference next to FIGS. **17**A-G, in another embodiment, an implant **400** is provided in which longitudinal struts **406** terminate in locking member **404** at a non-anchoring end of the stent **400**. The illustrated locking members **404** have a generally arrowhead-type shape that is enlarged relative to the adjacent strut **406**. Preferably a pull member **260***a* engages the stent **400** and pulls it through the compaction device **410** so that the implant **400** is compacted within the load tube **420**. The load tube and implant can then be removed from the pull member **260***a* and funnel portion **415** and loaded onto an inner tube **274***a* of a delivery device.

With particular reference to FIG. **17**B, the delivery device preferably includes the inner tube **274***a*, which is attached to a nose cone **276***a*. A support tube **430** is slidably disposed over the inner tube, and an outer sheath **300***a* is slidably disposed over the inner tube. Preferably an inner lumen diameter of the outer sheath **300***a* is greater than, but very close to, an outer diameter of the support tube **430**. A locking mechanism **432** is provided at the distal end of the support tube **430**. The locking mechanism **432** preferably comprises a tapered surface **434** that leads to a circumferential capture slot **440**. A plurality of guide slots **444** are provided and configured to generally align with struts **406** of the implant **400**. Preferably, the load tube **420** is sized such that the radially compacted implant **400** has an outer diameter less than an outer diameter of a proximal ridge of the tapered surface **434** immediately adjacent the capture slot **440**.

To load the compacted implant **400**, the support tube **430** is advanced so that the tapered surface **434** engages and deflects the locking members **404** and associated struts **406** of the implant **400**, as shown in FIG. **17**C. The support tube **430** continues to be advanced until the deflected locking members **404** clear the proximal edge of the tapered surface **434**, at which point the locking members **404** are no longer deflected, and will spring into the capture slot **440**, preferably with an audible “click”. When properly aligned, the struts **406** correspondingly spring into the guide slots **444** as depicted in FIG. **17**D, and the stent **400** and support tube **430** are now engaged.

With reference next to FIG. **17**E, the outer sheath **300***a* is next advanced distally so as to cover the capture slot **440** and thus securely capture the locking members **404** within the sheath **300***a*. As the sheath **300***a* continues to be advance distally, the compacted implant is transferred from the load tube **420** to the sheath **300***a*. Preferably a distal end of the sheath engages an end of the load tube **420** during such advancement, and thus anchor members that may in some embodiments be biased radially outwardly can be effectively transferred from within the load tube **420** to within the sheath **300***a*.

With additional reference to FIG. **17**F, preferably the nose cone **276***a* is sized so that the load tube **420** can be slid thereover and removed from the delivery device. In the illustrated embodiment the distal end of the sheath **300***a* at least partially overlaps the nose cone, and the sheath is shaped to provide a smooth transition from the distal end of the sheath to the nose cone. Of course, other embodiments may employ other structural interaction between the outer sheath and the nose cone, which may in some embodiments be removable.

In practice, the illustrated delivery device has operational features that may be similar to other embodiments discussed herein. For example, the implant can be partially deployed, but resheathed for repositioning. If necessary, the implant can also be resheathed for removal from the patient. In some such embodiments, in the event of complete resheathing, radially-outwardly-biased anchor members may not be able to be completely recaptured within the outer sheath **300***a* in the same position as originally provided. However, continued advancement of the sheath **300***a* after engagement of the anchor can have the effect of bending the anchor backwardly (distally) so that it is effectively captured between the sheath and nose cone. The delivery device can then be further manipulated, and even removed from the patient, with the entire implant, including anchor portions, fully resheathed.

Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while a number of variations of the invention have been shown and described in detail, other modifications, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. In fact, the embodiments specifically disclosed herein have been used as a vehicle to describe certain inventive features that can be employed alone or in various combinations in multiple additional embodiments. Thus, it is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the invention. For example, support tube embodiments such as in FIG. **14** can be modified to capture locking members within a capture slot as disclosed in FIG. **17**, and vice versa. Further, even though the stents described herein have been configured to foreshorten, certain features such as the methods and apparatus for controlled delivery as discussed in connection with FIGS. **12** and **13**, can be employed with self-expanding stents that don’t necessarily foreshorten, and don’t necessarily have anchoring features comparable to the embodiments disclosed herein. Further, the delivery device depicted in FIGS. **12** and **13** can be replaced with delivery devices employing principles as discussed in FIG. **14**, **15**, **17** or the like. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed invention. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

What is claimed is:

1. A replacement mitral valve configured to be delivered to a native mitral valve and secured relative to a native mitral valve annulus, the native mitral valve positioned between a left atrium and a left ventricle, the replacement mitral valve comprising:

an expandable frame comprising a proximal end and a distal end and having a longitudinal axis extending between the proximal end and the distal end, the expandable frame configured to radially expand and contract for deployment within the native mitral valve;

a first anchoring portion configured to at least partially engage an atrial side of the native mitral valve annulus, the first anchoring portion comprising a plurality of circumferentially-spaced tips connected by at least one row of circumferentially expansible elements extending continuously around the first anchoring portion, wherein when the expandable frame is in an expanded configuration, the first anchoring portion extends radially outwardly from a portion of the expandable frame that has a first cross-sectional dimension such that the at least one row of circumferentially expansible elements has a second cross-sectional dimension greater than the first cross-sectional dimension;

a second anchoring portion distal to the first anchoring portion and comprising a plurality of anchors extending from the expandable frame configured for placement on a ventricular side of the native mitral valve annulus, wherein when the expandable frame is in an expanded configuration, the plurality of anchors extend at least partially proximally toward the first anchoring portion; and

a valve body connected to the expandable frame;

wherein radial expansion of the expandable frame causes the first anchoring portion and the second anchoring portion to draw closer together; and

wherein, when the expandable frame is in the expanded configuration, tips of the plurality of anchors of the second anchoring portion extend to a third cross-sectional dimension which is at least about the same as the second cross-sectional dimension.

2. The replacement mitral valve of claim **1**, wherein the plurality of anchoring tips of the first anchoring portion extend radially outward when the expandable frame is in an expanded configuration.

3. The replacement mitral valve of claim **1**, wherein the plurality of tips of the first anchoring portion extend generally distally when the expandable frame is in an expanded configuration.

4. The replacement mitral valve of claim **1**, wherein the first anchoring portion extends radially outwardly from the portion of the expandable frame having the first cross-sectional dimension in a direction generally perpendicular to the longitudinal axis.

5. The replacement mitral valve of claim **1**, wherein when the expandable frame is in an expanded configuration, the expandable frame has a substantially constant outer diameter from where the plurality of anchors of the second anchoring portion connect to the expandable frame to where the first anchoring portion extends radially outwardly from the portion of the expandable frame having the first cross-sectional dimension.

6. The replacement mitral valve of claim **1**, wherein the plurality of anchors of the second anchoring portion extend from a foreshortening portion of the expandable frame.

7. The replacement mitral valve of claim **1**, wherein the first anchoring portion comprises a non-foreshortening portion that does not substantially foreshorten when the expandable frame radially expands.

8. The replacement mitral valve of claim **1**, wherein when the expandable frame is in an expanded configuration, the plurality of anchors of the second anchoring portion extend substantially parallel to the longitudinal axis of the expandable frame toward the first anchoring portion.

9. The replacement mitral valve of claim **1**, wherein when the expandable frame is in an expanded configuration, the plurality of anchors of the second anchoring portion extend distally away from the distal end of the expandable frame and then extend proximally toward the proximal end of the expandable frame.

10. The replacement mitral valve of claim **1**, wherein the plurality of anchors of the second anchoring portion are atraumatic.

11. The replacement mitral valve of claim **1**, wherein the at least one row of circumferentially expansible elements are arranged in a zig-zag pattern.

12. The replacement mitral valve of claim **1**, wherein the replacement mitral valve is shaped such that, after the replacement mitral valve has been delivered to the native mitral valve and expanded, at least a portion of the first anchoring portion contacts tissue on the atrial side of the native mitral valve annulus and at least a portion of the second anchoring portion contacts tissue on the ventricular side of the native mitral valve annulus.

13. The replacement mitral valve of claim **1**, wherein the expandable frame comprises a D-shaped cross-section.

14. A replacement mitral valve configured to be delivered to a native mitral valve and secured relative to a native mitral valve annulus, the native mitral valve positioned between a left atrium and a left ventricle, the replacement mitral valve comprising:

an expandable frame extending along a longitudinal axis between a first end and a second end, the expandable frame comprising a first portion and a second portion, the first portion being closer to the first end than the second portion is to the first end, and the second portion being closer to the second end than the first portion is to the second end, wherein the second portion comprises a plurality of foreshortening cells and the first portion comprises a plurality of struts having at least a portion thereof extending longitudinally from foreshortening cells of the second portion toward the first end of the expandable frame, wherein the first portion comprises a non-foreshortening portion that does not substantially foreshorten when the expandable frame is radially expanded;

a plurality of anchors connected to the second portion of the expandable frame, wherein the plurality of anchors extend radially outward from the expandable frame and extend in a direction generally toward the first end when the expandable frame is in an expanded configuration; and

a valve body attached to the expandable frame;

wherein when the expandable frame is in an expanded configuration, the first portion comprises an anchoring portion configured to engage an atrial side of the native mitral valve annulus that extends radially outwardly from the second portion in a direction generally perpendicular to the longitudinal axis, and

wherein the replacement mitral valve is shaped such that, after the replacement mitral valve has been delivered to the native mitral valve and expanded, at least a portion of the anchoring portion contacts tissue on the atrial side of the native mitral valve annulus and at least some of the plurality of anchors contact tissue on the ventricular side of the native mitral valve annulus.

15. The replacement mitral valve of claim **14**, wherein the first portion comprises a plurality of anchoring tips configured to engage the valve on an atrial side of the native mitral valve annulus when the expandable frame is in an expanded configuration.

16. The replacement mitral valve of claim **14**, wherein the first portion comprises at least one row of circumferentially expansible elements, and wherein the struts extend transversely across the at least one row.

17. The replacement mitral valve of claim **14**, wherein the plurality of anchors are atraumatic.

18. The replacement mitral valve of claim 14, wherein when the expandable frame is in an expanded configuration, each of the struts lies in a plane parallel to and intersecting the longitudinal axis.

19. The replacement mitral valve of claim 14, wherein when the expandable frame is in an expanded configuration, the first portion of the expandable frame has a cross-sectional dimension greater than a cross-sectional dimension of the second portion of the expandable frame.

20. A replacement mitral valve configured to be delivered to a native mitral valve and secured relative to a native mitral valve annulus, the native mitral valve positioned between a left atrium and a left ventricle, the replacement mitral valve comprising:

an expandable frame comprising a proximal end and a distal end and having a longitudinal axis extending between the proximal end and the distal end, the expandable frame configured to radially expand and contract for deployment within the native mitral valve;

a first anchoring portion sized to at least partially engage an atrial side of the native mitral valve annulus, wherein when the expandable frame is in an expanded configuration:

a first section of the first anchoring portion extends radially outwardly of the longitudinal axis and at least partially proximally; and

a second section of the first anchoring portion proximal to the first section extends radially inwardly from the first section towards the longitudinal axis and at least partially proximally;

a second anchoring portion distal to the first anchoring portion and comprising a plurality of anchors extending from the expandable frame sized for placement on a ventricular side of the native mitral valve annulus, wherein when the expandable frame is in an expanded configuration, the plurality of anchors extend at least partially proximally toward the first anchoring portion; and

a valve body connected to the expandable frame.

21. The replacement mitral valve of claim 20, wherein the replacement mitral valve is shaped such that, after the replacement mitral valve has been delivered to the native mitral valve and expanded, at least a portion of the first anchoring portion contacts tissue on the atrial side of the native mitral valve annulus and at least a portion of the second anchoring portion contacts tissue on the ventricular side of the native mitral valve annulus.

22. The replacement mitral valve of claim 21, wherein the replacement mitral valve is shaped such that, after the replacement mitral valve has been delivered to the native mitral valve and expanded, at least a portion of the second anchoring portion contacts at least one of the native mitral valve annulus and leaflets of the native mitral valve.

23. The replacement mitral valve of claim 21, wherein the replacement mitral valve is shaped such that, after the replacement mitral valve has been delivered to the native mitral valve and expanded, the expandable frame comprises a cylindrical portion extending within a chamber of the heart with at least a portion of the valve body positioned within the cylindrical portion such that the valve body is located substantially outside of the native valve annulus.

24. The replacement mitral valve of claim 20, wherein the first section of the first anchoring portion extends radially outwardly to define a shoulder.

25. The replacement mitral valve of claim 20, wherein when the expandable frame is in an expanded configuration, the expandable frame has a substantially constant outer diameter from where the plurality of anchors of the second anchoring portion connect to the expandable frame to where the first section of the first anchoring portion extends radially outwardly of the longitudinal axis.

26. The replacement mitral valve of claim 20, wherein when the expandable frame is in an expanded configuration, the second section of the first anchoring portion, after extending radially inwardly from the first section towards the longitudinal axis and at least partially proximally, extends in a direction generally parallel to the longitudinal axis.

27. The replacement mitral valve of claim 20, wherein when the expandable frame is in an expanded configuration, a cross-sectional dimension of the proximal end of the expandable frame is less than a cross-sectional dimension of the second anchoring portion.

28. The replacement mitral valve of claim 20, wherein when the expandable frame is in an expanded configuration, a cross-sectional dimension of the proximal end of the expandable frame is about the same as a cross-sectional dimension of the distal end of the expandable frame.

29. The replacement mitral valve of claim 20, wherein when the frame is in an expanded configuration, the expandable frame comprises a cylindrical portion which extends away from both the first and second anchoring portions towards one of the ends of the frame, wherein at least a portion of the valve body is positioned within the cylindrical portion when the expandable frame is in an expanded configuration.

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